UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended September 30, 2020
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: 001-39593

Shattuck Labs, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**81-2575858**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**

1018 W. 11th Street, Suite 100
Austin, TX 78703
(919) 864-2700
(Address of principal executive offices including zip code)
Former name, former address and former fiscal year, if changed since last report: N/A

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

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

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

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

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

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

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

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

As of November 1, 2020, the registrant had 41,744,237 shares of common stock, $0.0001 par value per share, outstanding.

SHATTUCK LABS, INC.
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CAUTIONARY NOTE ABOUT FORWARD-LOOKING STATEMENTS

This quarterly report contains "forward-looking statements" within the meaning of the federal securities laws, which statements are subject to substantial risks and uncertainties and are based on estimates and assumptions. All statements, including statements concerning our plans, objectives, goals, strategies, future events, future revenues or performance, financing needs, plans or intentions relating to products and markets, and business trends and other information referred to under the sections entitled "Risk Factors," and "Management's Discussion and Analysis of Financial Condition and Results of Operations" are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "design," "estimate," "predict," "potential," "plan," or the negative of these terms, and similar expressions intended to identify forward-looking statements. Forward-looking statements are not historical facts, and reflect our current views with respect to future events. Given the significant uncertainties, you should not place undue reliance on these forward-looking statements.

There are a number of risks, uncertainties and other factors that could cause our actual results to differ materially from the forward-looking statements expressed or implied in this filing. Such risks, uncertainties and other factors include, among others, the following risks, uncertainties and factors:

- the recent and ongoing COVID-19 pandemic and associated shelter-in-place orders;
- the timing of the initiation, progress, and expected results of our preclinical studies, our clinical trials and our research and development programs;
- our ability to retain the continued service of our key executives and to identify, hire, and retain additional qualified professionals;
- our ability to advance product candidates into, and successfully complete, preclinical studies and clinical trials;
- the timing or likelihood of regulatory filings and approvals;
- the commercialization of our product candidates, if approved;
- our ability and the potential to successfully manufacture and supply our product candidates for clinical trials and for commercial use, if approved;
- the pricing, coverage, and reimbursement of our product candidates, if approved;
- the implementation of our business model, strategic plans for our business, and product candidates;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our technology platforms, including our ARC and GADLEN product candidates and other product candidates, including the defense of such intellectual property rights;
- our potential need to obtain additional licenses of third-party technology that may not be available to us or are available only on commercially unreasonable terms, and which may cause us to operate our business in a more costly or otherwise adverse manner that was not anticipated;
- our ability to enter into strategic arrangements and/or collaborations and to realize the potential benefits of such arrangements;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- our estimates regarding the market opportunity for our product candidates, if approved;
- our estimates regarding expenses, capital requirements, and needs for additional financing and our ability to obtain additional capital;
- our financial performance; and

- developments relating to our competitors and our industry, including competing product candidates and therapies.

There may be other factors that may cause our actual results to differ materially from the forward-looking statements expressed or implied in this filing, including factors disclosed in “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” You should evaluate all forward-looking statements made in this filing in the context of these risks and uncertainties.

We caution you that the risks, uncertainties, and other factors referred to above and elsewhere in this filing may not contain all of the risks, uncertainties and other factors that may affect our future results and operations. Moreover, new risks will emerge from time to time. It is not possible for our management to predict all risks. In addition, we cannot assure you that we will realize the results, benefits or developments that we expect or anticipate or, even if substantially realized, that they will result in the consequences or affect us or our business in the way expected.

Any forward-looking statements contained in this Quarterly Report on Form 10-Q speak only as of the date hereof and not of any future date, and we expressly disclaim any intent to update any forward-looking statements, whether as a result of new information, future events or otherwise.

PART I. - FINANCIAL INFORMATION

Item 1. Financial Statements

SHATTUCK LABS, INC.
CONDENSED BALANCE SHEETS
(Unaudited)
(In thousands, except share and per share amounts)

	September 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 128,600	$ 7,013
Short-term investments	6,339	32,074
Prepaid expenses and other current assets	7,315	3,355
Total current assets	142,254	42,442
Property and equipment, net	2,515	2,437
Other assets	89	90
Total assets	$ 144,858	$ 44,969
Liabilities, redeemable convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 1,350	$ 3,051
Accrued expenses	6,518	4,039
Deferred revenue – related party	8,613	12,894
Total current liabilities	16,481	19,984
Deferred revenue – related party net of current portion	19,722	9,571
Deferred rent	911	898
Total liabilities	37,114	30,453
Commitments and contingencies (Note 5)		
Redeemable convertible preferred stock:		
Series A redeemable convertible preferred stock, $0.0001 par value: 1,093,019 shares authorized, issued and outstanding as of September 30, 2020 and December 31, 2019; (liquidation value of $68,286 as of September 30, 2020)	49,064	49,064
Series B redeemable convertible preferred stock, $0.0001 par value: 550,571 shares authorized as of September 30, 2020 and December 31, 2019; 550,571 and none issued and outstanding as of September 30, 2020 and December 31, 2019, respectively; (liquidation value of $34,620 as of September 30, 2020)	34,427	—
Series B-1 redeemable convertible preferred stock, $0.0001 par value: 1,319,964 shares authorized as of September 30, 2020 and December 31, 2019, 1,319,964 and none issued and outstanding as of September 30, 2020 and December 31, 2019, respectively; (liquidation value of $83,000 as of September 30, 2020)	82,613	—
Stockholders' deficit:		
Common stock, $0.0001 par value: 10,000,000 shares authorized; 7,796,069 and 7,632,777 shares issued and 7,779,280 and 7,600,877 shares outstanding at September 30, 2020 and December 31, 2019, respectively	1	1
Additional paid-in capital	1,730	887
Accumulated other comprehensive income (loss)	(10)	54
Accumulated deficit	(60,081)	(35,490)
Total stockholders' deficit	(58,360)	(34,548)
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	$ 144,858	$ 44,969

See accompanying notes to unaudited interim condensed financial statements

SHATTUCK LABS, INC.
CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Collaboration revenue – related party	$ 2,435	$ 1,784	$ 8,592	$ 7,066
Operating expenses:				
Research and development	11,804	7,945	27,696	20,447
General and administrative	2,470	1,366	5,816	4,062
Expense from operations	14,274	9,311	33,512	24,509
Loss from operations	(11,839)	(7,527)	(24,920)	(17,443)
Other income (expense):				
Interest income	86	279	474	902
Other	(76)	(31)	(145)	(72)
Total other income	10	248	329	830
Net loss	$ (11,829)	$ (7,279)	$ (24,591)	$ (16,613)
Unrealized gain (loss) on short-term investments	(28)	10	(64)	119
Comprehensive loss	$ (11,857)	$ (7,269)	$ (24,655)	$ (16,494)
Net loss per share – basic and diluted	$ (1.54)	$ (0.96)	$ (3.21)	$ (2.20)
Weighted-average shares outstanding – basic and diluted	7,700,371	7,572,746	7,656,077	7,543,831

See accompanying notes to unaudited interim condensed financial statements

SHATTUCK LABS, INC.
CONDENSED STATEMENT OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(Unaudited)
(In thousands, except share amounts)

Three and Nine Months Ended September 30, 2020

	Series A Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Series B-1 Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at January 1, 2020	1,093,019	$ 49,064	—	$ —	—	$ —	7,600,877	$ 1	$ 887	$ 54	$ (35,490)	(34,548)
Sale of Series B redeemable convertible preferred stock, net of issuance costs	—	—	550,571	34,427	—	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	180	—	—	180
Unrealized gain on investments	—	—	—	—	—	—	—	—	—	61	—	61
Exercise of stock options	—	—	—	—	—	—	28,113	—	—	—	—	—
Vesting of common stock previously subject to vesting	—	—	—	—	—	—	5,037	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	—	—	(6,788)	(6,788)
Balance at March 31, 2020	1,093,019	$ 49,064	550,571	$ 34,427	—	$ —	7,634,027	$ 1	$ 1,067	$ 115	$ (42,278)	$ (41,095)
Sale of Series B-1 redeemable convertible preferred stock, net of issuance costs	—	—	—	—	1,319,964	82,618	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	137	—	—	137
Unrealized loss on investments	—	—	—	—	—	—	—	—	—	(97)	—	(97)
Exercise of stock options	—	—	—	—	—	—	20,131	—	—	—	—	—
Vesting of common stock previously subject to vesting	—	—	—	—	—	—	5,037	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	—	—	(5,974)	(5,974)
Balance at June 30, 2020	1,093,019	$ 49,064	550,571	$ 34,427	1,319,964	$ 82,618	7,659,195	$ 1	$ 1,204	$ 18	$ (48,252)	(47,029)
Series B-1 additional issuance costs	—	—	—	—	—	(5)	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	312	—	—	312
Unrealized loss on investments	—	—	—	—	—	—	—	—	—	(28)	—	(28)
Exercise of stock options	—	—	—	—	—	—	115,048	—	214	—	—	214
Vesting of common stock previously subject to vesting	—	—	—	—	—	—	5,037	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	—	—	(11,829)	(11,829)
Balance at September 30, 2020	1,093,019	$ 49,064	550,571	$ 34,427	1,319,964	$ 82,613	7,779,280	$ 1	$ 1,730	$ (10)	$ (60,081)	(58,360)

See accompanying notes to unaudited interim condensed financial statements

SHATTUCK LABS, INC.
CONDENSED STATEMENT OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(Continued)
(Unaudited)
(In thousands, except share amounts)

	Three and Nine Months Ended September 30, 2019											
	Series A Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Series B-1 Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at January 1, 2019	1,093,019	$ 49,064	—	$ —	—	$ —	7,495,988	$ 1	$ 426	$ —	$ (11,508)	(11,081)
Stock-based compensation expense	—	—	—	—	—	—	—	—	66	—	—	66
Unrealized gain on investments	—	—	—	—	—	—	—	—	—	44	—	44
Exercise of stock options	—	—	—	—	—	—	25,488	—	—	—	—	—
Vesting of common stock previously subject to vesting	—	—	—	—	—	—	5,037	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	—	—	(3,449)	(3,449)
Balance at March 31, 2019	1,093,019	$ 49,064	—	$ —	—	$ —	7,526,513	$ 1	$ 492	$ 44	$ (14,957)	$ (14,420)
Stock-based compensation expense	—	—	—	—	—	—	—	—	87	—	—	87
Unrealized gain on investments	—	—	—	—	—	—	—	—	—	65	—	65
Exercise of stock options	—	—	—	—	—	—	24,401	—	—	—	—	—
Vesting of common stock previously subject to vesting	—	—	—	—	—	—	5,037	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	—	—	(5,885)	(5,885)
Balance at June 30, 2019	1,093,019	$ 49,064	—	$ —	—	$ —	7,555,951	$ 1	$ 579	$ 109	$ (20,842)	(20,153)
Stock-based compensation expense	—	—	—	—	—	—	—	—	144	—	—	144
Unrealized gain on investments	—	—	—	—	—	—	—	—	—	10	—	10
Exercise of stock options	—	—	—	—	—	—	26,159	—	—	—	—	—
Vesting of common stock previously subject to vesting	—	—	—	—	—	—	5,037	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	—	—	(7,279)	(7,279)
Balance at September 30, 2019	1,093,019	$ 49,064	—	$ —	—	$ —	7,587,147	$ 1	$ 723	$ 119	$ (28,121)	(27,278)

See accompanying notes to unaudited interim condensed financial statements

SHATTUCK LABS, INC.
CONDENSED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2020	**2019**
Cash flows from operations:		
Net loss	$ (24,591)	$ (16,613)
Adjustments to reconcile net loss to net cash used in operations:		
Depreciation	448	403
Stock-based compensation	629	297
Accretion of short-term investments	(22)	(82)
Changes in operating assets and liabilities:		
Accounts receivable	—	207
Prepaid expenses and other current assets	(2,214)	1,649
Non-current assets	(33)	—
Accounts payable	(1,701)	(1,223)
Accrued expenses	1,985	1,169
Deferred revenue—related party	5,870	(146)
Deferred rent	13	985
Net cash used in operating activities	(19,616)	(13,354)
Cash flows from investing activities:		
Purchase of property and equipment	(526)	(445)
Sale and maturities of short-term investments	31,270	32,642
Purchases of short-term investments	(5,578)	(35,259)
Net cash (used in) provided by investing activities	25,166	(3,062)
Cash flows from financing activities:		
Payments for public offering costs	(1,251)	—
Proceeds from the sale of Series B redeemable convertible preferred stock, net of issuance costs	34,461	—
Proceeds from the sale of Series B-1 redeemable convertible preferred stock, net of issuance costs	82,613	—
Exercise of stock options	214	—
Net cash provided by financing activities	116,037	—
Net increase (decrease) in cash and cash equivalents	121,587	(16,416)
Cash and cash equivalents, beginning of period	7,013	31,644
Cash and cash equivalents, end of period	$ 128,600	$ 15,228
Supplemental disclosures of non-cash financial activities:		
Unrealized gain (loss) on short-term investments	$ (64)	$ 119
Accrued public offering costs in other current assets	$ 495	$ —

See accompanying notes to unaudited interim condensed financial statements

SHATTUCK LABS, INC.
NOTES TO UNAUDITED INTERIM FINANCIAL STATEMENTS

1. Organization and Description of Business

Shattuck Labs, Inc. (the "Company") was incorporated in 2016 in the State of Delaware and is a clinical-stage biopharmaceutical company developing dual-sided fusion proteins, including its ARC® and GADLEN™ platforms, as novel classes of biologic medicines capable of multifunctional activity with potential applications in oncology and inflammatory diseases. Using its proprietary technology, the Company is building a pipeline of therapeutics, initially focused on the treatment of solid tumors and hematologic malignancies. The Company has two clinical-stage product candidates, SL-172154 and SL-279252. In addition, the Company has several ARC compounds in preclinical development.

Liquidity

The Company has incurred losses and negative cash flows from operations since inception and has an accumulated deficit of $60.1 million as of September 30, 2020. The Company anticipates incurring additional losses and negative cash flows from operations until such time, if ever, that it can generate significant sales of its product candidates currently in development, and is highly dependent on its ability to find additional sources of funding in the form of licensing of its technology, collaboration agreements, and/or debt and equity financing. The Company's ability to fund its planned clinical operations, research and development, and commercialization of its product candidates is expected to depend on the amount and timing of cash receipts from these funding sources. Adequate additional funding may not be available to the Company on acceptable terms, or at all. The failure to raise funds as and when needed could have a negative impact on the Company's financial condition and ability to pursue its business strategies. Management believes that the Company's cash and cash equivalents and short-term investments of $134.9 million as of September 30, 2020, in addition to the $213.5 million of net proceeds from our initial public offering, are sufficient to fund the projected operations of the Company through at least the end of 2024.

On March 10, 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. The virus and actions taken to mitigate its spread have had, and are expected to continue to have, a broad adverse impact on the economies and financial markets of many countries, including the geographical areas in which the Company operates and conducts its business and which the Company's partners operate and conduct their business. The Company is currently following the recommendations of local health authorities to minimize exposure risk for its team members and visitors. However, the scale and scope of this pandemic is unknown and the duration of the business disruption and related financial impact cannot be reasonably estimated at this time. While we have implemented specific business continuity plans to reduce the potential impact of COVID-19, there is no guarantee that the Company's continuity plans will be successful.

The Company has already experienced certain disruptions to its business such as work-from-home-orders for offices and similar disruptions have occurred for its partners. Specifically, the outbreak has caused disruptions in enrollment and treatment of patients in clinical trials in process, and slowdowns and shutdowns of the laboratories and other service providers that are being relied upon in the development of the Company's product candidates.

The extent to which COVID-19 or any other health epidemic may impact the Company's results will depend on future developments, which are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others. Accordingly, COVID-19 could have a material adverse effect on the Company's business, results of operations and financial condition.

2. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited interim financial statements have been prepared in conformity with U.S. generally accepted accounting principles ("U.S. GAAP") for interim financial information.

Unaudited Interim Financial Statements

In the opinion of management, the accompanying interim financial statements include all normal and recurring adjustments (which consist primarily of accruals, estimates and assumptions that impact the financial

statements) considered necessary to present fairly the Company's financial position as of September 30, 2020 and its results of operations, statement of changes in redeemable convertible preferred stock and stockholder's deficit and cash flows for the nine months ended September 30, 2020 and 2019. Operating results for the nine months ended September 30, 2020 are not necessarily indicative of the results that may be expected for the year ending December 31, 2020. The interim financial statements, presented herein, do not contain the required disclosures under U.S. GAAP for annual financial statements. The accompanying unaudited interim financial statements should be read in conjunction with the annual audited financial statements and related notes as of and for the year ended December 31, 2019.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Significant estimates and assumptions reflected in these financial statements include, but are not limited to, revenue recognition, the accrual of research and development expenses, and the valuation of stock-based awards. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from management's estimates.

Fair Value of Financial Instruments

Fair value is defined as the price that would be received upon the sale of an asset or paid upon the transfer of a liability in an orderly transaction between market participants at the measurement date and in the principal or most advantageous market for that asset or liability. Fair value measurements are classified and disclosed in one of the following categories:

- Level 1: Observable inputs such as quoted prices in active markets for identical assets the reporting entity has the ability to access as of the measurement date;
- Level 2: Inputs, other than quoted prices in active markets, that are observable either directly or indirectly; and
- Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

Fair value measurements are classified based on the lowest level of input that is significant to the measurement. The Company's assessment of the significance of a particular input to the fair value measurement requires judgment, which may affect the valuation of the assets and liabilities and their placement within the fair value hierarchy levels. The determination of the fair values stated below takes into account the market for its financial assets and liabilities, the associated credit risk and other factors as required. The Company considers active markets as those in which transactions for the assets or liabilities occur in sufficient frequency and volume to provide pricing information on an ongoing basis.

Management believes that the carrying amounts of the Company's financial instruments, including accounts payable, approximate fair value due to the short-term nature of those instruments. Short-term investments are recorded at their estimated fair value.

Concentration of Risk

Financial instruments that potentially subject the Company to concentrations of credit risk primarily consist of cash, cash equivalents, and short-term investments. The Company maintains its cash and cash equivalents at one accredited financial institution in amounts that exceed federally-insured limits. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships. The Company invests in only highly rated debt securities that management believes protects the Company from risk of default and impairment of value.

All of the Company's revenue is derived from its collaboration agreement with Millennium Pharmaceuticals, Inc., a wholly owned subsidiary of Takeda Pharmaceutical Company Limited (see Note 8).

The Company is highly dependent on a third-party manufacturer to supply drug products for its research and development activities of its programs, including clinical trials and non-clinical studies. These programs could be adversely affected by a significant interruption in the supply of such drug products.

The Company is highly dependent on two contract research organizations ("CROs") to manage its clinical trials. These programs could be adversely affected by a significant disruption in services provided by the CROs.

Cash Equivalents

The Company considers all demand deposits with financial institutions and all highly liquid investments with maturities of ninety days or less at the date of purchase to be cash and cash equivalents. Cash equivalents consist of $6.5 million held in a money market fund and $0.5 million held in an operating account at December 31, 2019 and $126.3 million held in a money market fund and $2.3 million held in an operating account at September 30, 2020, and are carried at fair value of the investment based on quoted market prices.

Short-Term Investments

Short-term investments consist of debt securities with a maturity of greater than three months when acquired. The Company classifies its short-term investments at the time of purchase as available-for-sale securities. Available-for-sale securities are carried at fair value. Unrealized gains and losses on available-for-sale securities are reported in accumulated other comprehensive income, a component of stockholders' deficit, until realized.

Deferred Offering Costs

The Company capitalizes certain legal, accounting, and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs will be recorded as a reduction of additional paid-in capital generated as a result of the offering. Should the equity financing no longer be considered probable of being consummated, all deferred offering costs would be charged to operating expenses in the statement of operations and comprehensive loss. Deferred offering costs were $0.1 million and $1.8 million at December 31, 2019 and September 30, 2020, respectively.

Series A, Series B and Series B-1 Redeemable Convertible Preferred Stock

The Company records shares of redeemable convertible preferred stock at their respective fair values on the date of issuance, net of issuance costs. The redeemable convertible preferred stock is recorded outside of stockholders' equity on the balance sheet because the shares contain liquidation features that are not solely within the Company's control. The Company has elected not to adjust the carrying values of the redeemable convertible preferred stock to the liquidation preferences of such shares because of the uncertainty of whether or when such an event would occur. Subsequent adjustments to increase the carrying value to the liquidation preferences will be made only when it becomes probable that such a liquidation event will occur. See Note 6 for a discussion of the redeemable convertible preferred stock.

Revenue Recognition

Collaboration revenue is recognized in accordance with ASC 606, *Revenue from Contracts with Customers* (ASC 606). Arrangements with collaborators may include licenses to intellectual property, research and development services, manufacturing services for clinical and commercial supply, and participation on joint steering committees. The Company evaluates the promised goods or services in the contract to determine which promises, or group of promises, represent performance obligations. In contemplation of whether a promised good or service meets the criteria required of a performance obligation, the Company considers the stage of development of the underlying intellectual property, the capabilities and expertise of the customer relative to the underlying intellectual property, and whether the promised goods or services are integral to or dependent on other promises in the contract. When accounting for an arrangement that contains multiple performance obligations, the Company must develop judgmental assumptions, which may include market conditions, reimbursement rates for personnel costs, development timelines and probabilities of regulatory success to determine the stand-alone selling price for each performance obligation identified in the contract.

Upon the amendment of an existing agreement, the Company evaluates whether the amendment represents a modification to an existing contract which would be recorded through a cumulative catch-up to revenue or a separate

contract. If it is determined that it is a separate contract, the Company will evaluate the necessary revenue recognition through the five-step process described below.

When the Company concludes that a contract should be accounted for as a combined performance obligation and recognized over time, the Company must then determine the period over which revenue should be recognized and the method by which to measure revenue. The Company generally recognizes revenue using a cost-based input method.

The Company recognizes collaboration revenue when its customer or collaborator obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, it performs the following five steps:

i. identify the contract(s) with a customer;

ii. identify the performance obligations in the contract;

iii. determine the transaction price;

iv. allocate the transaction price to the performance obligations within the contract and;

v. recognize revenue when (or as) the entity satisfies a performance obligation.

The Company only applies the five-step model to contracts when it determines that it is probable it will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer.

At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within the contract to determine whether each promised good or service is a performance obligation. The promised goods or services in the Company's arrangements may consist of a license, or options to license, the Company's intellectual property and research, development and manufacturing services. The Company may provide options to additional items in such arrangements, which are accounted for as separate contracts when the customer elects to exercise such options, unless the option provides a material right to the customer. Performance obligations are promises in a contract to transfer a distinct good or service to the customer that (i) the customer can benefit from on its own or together with other readily available resources, and (ii) is separately identifiable from other promises in the contract. Goods or services that are not individually distinct performance obligations are combined with other promised goods or services until such combined group of promises meet the requirements of a performance obligation.

The Company determines transaction price based on the amount of consideration the Company expects to receive for transferring the promised goods or services in the contract. Consideration may be fixed, variable, or a combination of both. At contract inception for arrangements that include variable consideration, the Company estimates the probability and extent of consideration it expects to receive under the contract utilizing either the most likely amount method or expected amount method, whichever best estimates the amount expected to be received. The Company then considers any constraints on the variable consideration and includes in the transaction price variable consideration to the extent it is deemed probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

The Company then allocates the transaction price to each performance obligation based on the relative standalone selling price and recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) control is transferred to the customer and the performance obligation is satisfied. For performance obligations which consist of licenses and other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

The Company records amounts as accounts receivable when the right to consideration is deemed unconditional. When consideration is received, or such consideration is unconditionally due, from a customer prior

to transferring goods or services to the customer under the terms of a contract, a contract liability is recorded as deferred revenue.

Amounts received prior to satisfying the revenue recognition criteria are recognized as deferred revenue in the Company's accompanying balance sheet. Deferred revenues expected to be recognized as revenue within the 12 months following the balance sheet date are classified as a current liability. Deferred revenues not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as non-current liabilities.

The Company's collaboration revenue arrangements may include the following:

Up-front License Fees: If a license is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from nonrefundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone Payments: At the inception of an agreement that includes research and development milestone payments, the Company evaluates each milestone to determine when and how much of the milestone to include in the transaction price. The Company first estimates the amount of the milestone payment that the Company could receive using either the expected value or the most likely amount approach. The Company primarily uses the most-likely amount approach as that approach is generally most predictive for milestone payments with a binary outcome. Then, the Company considers whether any portion of that estimated amount is subject to the variable consideration constraint (that is, whether it is probable that a significant reversal of cumulative revenue would not occur upon resolution of the uncertainty.) The Company updates the estimate of variable consideration included in the transaction price at each reporting date which includes updating the assessment of the likely amount of consideration and the application of the constraint to reflect current facts and circumstances.

Royalties: For arrangements that include sales-based royalties, including milestone payments based on a level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company will recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any revenue related to sales-based royalties or milestone payments based on the level of sales.

To date, the Company has not granted a development and commercialization license nor recognized any revenue related to licenses, sales-based royalties or milestone payments based on the level of sales.

Research and Development Services: The Company will record costs associated with development and process optimization activities as research and development expenses in the statement of operations and comprehensive loss consistent with ASC 730, *Research and Development.* The Company considered the guidance in ASC 808, *Collaborative Agreements* and will recognize the payments received from these agreements as revenue when the related costs are incurred.

Research and Development Costs

Research and development cost are expensed as incurred, and include salaries, stock-based compensation and other personnel-related costs, equipment and supplies, preclinical studies, clinical trials, and manufacturing development activities.

A substantial portion of the Company's ongoing research and development activities are conducted by third-party service providers, including contract research and manufacturing organizations. The Company accrues for expenses resulting from obligations under agreements with CROs, contract manufacturing organizations ("CMOs"), and other outside service providers for which payment flows do not match the periods over which materials or services are provided to the Company. Accruals are recorded based on estimates of services received and efforts expended pursuant to agreements established with CROs, CMOs, and other outside service providers. These estimates are typically based on contracted amounts applied to the proportion of work performed and determined through analysis with internal personnel and external service providers as to the progress or stage of completion of

the services. The Company makes significant judgements and estimates in determining the accrual and/or prepaid balance in each reporting period. In the event advance payments are made to a CRO, CMO, or outside service provider, the payments will be recorded as a prepaid asset which will be amortized as the contracted services are performed. As actual costs become known, the Company adjusts its accruals and prepaid assets accordingly. Inputs, such as the services performed, the number of patients enrolled, or the study duration, may vary from the Company's estimates, resulting in adjustments to research and development expense in future periods. Changes in these estimates that result in material changes to the Company's accruals could materially affect the Company's results of operations.

Net Loss Per Share

Basic loss per share of common stock is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during each period. Diluted loss per share of common stock includes the effect, if any, from the potential exercise or conversion of securities, such as redeemable convertible preferred stock, stock options and restricted stock, which would result in the issuance of incremental shares of common stock. For diluted net loss per share, the weighted-average number of shares of common stock is the same for basic net loss per share due to the fact that when a net loss exists, dilutive securities are not included in the calculation as the impact is anti-dilutive.

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares of common stock outstanding, as they would be anti-dilutive:

	Nine Months Ended September 30,	
	2020	**2019**
Redeemable convertible preferred stock on an as converted to common stock basis	20,300,253	7,487,151
Stock options	2,538,225	1,255,543
Unvested restricted stock	16,789	36,937
	22,855,267	8,779,631

Other Comprehensive Income (Loss)

Other comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Other comprehensive loss is comprised of the net loss and unrealized gains on short-term investments.

Recently Adopted Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board (the "FASB") issued ASU No. 2016-13, *Financial Instruments-Credit Losses ("ASC 326")*: Measurement of Credit Losses on Financial Instruments (ASU 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 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. ASU 2016-13 became effective for the Company during the first quarter of 2020. The Company adopted this pronouncement and it did not have a material impact on the financial statements or related disclosures.

In August 2018, the FASB issued ASU No. 2018-13, *Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurements*, which changes the fair value measurement disclosure requirements of ASC 820, Fair Value Measurements and Disclosures ("ASC 820"). The goal of the ASU is to improve the effectiveness of ASC 820's disclosure requirements. The standard is applicable to the Company for the fiscal year beginning January 1, 2020, and interim periods within that year. The Company adopted this pronouncement and it did not have a material impact on the financial statements or related disclosures.

Recently Issued Accounting Pronouncements (not yet adopted)

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (ASC 842) which requires a lessee to record a right-of-use asset and a corresponding lease liability on the balance sheet for all leases with terms longer than 12

months. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. As the Company has elected to use the extended transition period for complying with new or revised accounting standards as available under the JOBS Act, the standard is effective for the Company beginning January 1, 2022, with early adoption permitted. The Company is currently evaluating the expected impact that the standard could have on its financial statements and related disclosures.

3. Short-Term Investments

The Company classifies its debt securities as short-term investments. Debt securities are comprised of highly liquid investments with minimum "A" rated securities and consist of U.S. Treasury, agency bonds and corporate entity commercial paper with maturities of more than three months but less than one year at the date of purchase. Debt securities as of September 30, 2020 have an average maturity of 0.1 years. The debt securities are reported at fair value with unrealized gains or losses recorded in accumulated other comprehensive income in the balance sheets.

The following table represents the Company's available for sale short-term investments by major security type (in thousands):

	September 30, 2020		
	Amortized Cost	Gross Unrealized Gain/(Loss)	Total Fair Value
Short-term investments			
Corporate securities	$ 2,350	$ (17)	$ 2,333
U.S. government securities	3,999	7	4,006
Total short-term investments	$ 6,349	$ (10)	$ 6,339

	December 31, 2019		
	Amortized Cost	Gross Unrealized Gain/(Loss)	Total Fair Value
Short-term investments			
Corporate securities	$ 5,375	$ (17)	$ 5,358
U.S. government securities	26,645	71	26,716
Total short-term investments	$ 32,020	$ 54	$ 32,074

The Company's short-term investment instruments and cash and cash equivalents are classified using Level 1 inputs within the fair value hierarchy and are valued using quoted market prices, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency.

4. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	September 30, 2020	December 31, 2019
Research contract costs	$ 4,539	$ 2,648
Compensation	1,188	966
Other	791	425
	$ 6,518	$ 4,039

5. Commitments and Contingencies

Operating Leases

On July 24, 2020, the Company entered into an amendment to the lease for the office space in Durham, North Carolina. The amendment expanded the existing leased space. Future minimum payments inclusive of the amended

lease, by year and in aggregate, under non-cancelable operating leases consist of the following as of September 30, 2020 (in thousands):

2020	$	73
2021		625
2022		730
2023		753
2024		775
Thereafter		3,340
Total minimum lease payments	$	6,296

Heat License Agreement

In connection with a license agreement with Heat Biologics Inc. (“Heat”), the Company is required to make payments of up to $20.6 million in aggregate for the achievement of specified development, regulatory and commercial sales milestones for certain licensed products. The Company is required to pay Heat a percentage of any upfront fees or other non-royalty payments received that are not tied to milestone events under any sublicense of the licensed products. The Company is also required to pay Heat a royalty on all of its worldwide net sales, those of its affiliates and sublicenses of certain licensed products in the low single digits. The Company has not recorded a liability for the payments aforementioned given the achievement of specified development, regulatory and commercial sales milestones for certain licensed products is not probable as of the balance sheet date.

Litigation

From time to time, the Company may become involved in various legal actions arising in the ordinary course of business. As of September 30, 2020, management was not aware of any existing, pending, or threatened legal actions that would have a material impact on the financial position, results of operations, or cash flows of the Company.

Contractual Obligations

Contractual obligations represent future cash commitments and liabilities under agreements with third parties, and exclude contingent liabilities for which the Company cannot reasonably predict future payment. The Company’s contractual obligations result primarily from obligations for various contract manufacturing organizations and clinical research organizations, which include potential payments we may be required to make under our agreements. The contracts also contain variable costs and milestones that are hard to predict as they are based on such things as patients enrolled and clinical trial sites. The timing of payments and actual amounts paid under contract manufacturing organization, or CMO, and CRO agreements may be different depending on the timing of receipt of goods or services or changes to agreed-upon terms or amounts for some obligations. Also, those agreements are cancelable upon written notice by the Company and, therefore, not long-term liabilities.

6. Preferred Stock

During the nine months ended September 30, 2020, the Company entered into various stock purchase agreements with new and existing investors pursuant to which the Company sold an aggregate 550,571 shares of the Company’s Series B redeemable convertible preferred stock (“Series B”) and 1,319,964 shares of Series B-1 redeemable convertible preferred stock (“Series B-1”) at $62.88051 per share for aggregate gross proceeds of $117.6 million. Transaction fees of $0.6 million were recorded as a reduction of the carrying value of the Series B and the Series B-1.

The following is a summary of the rights, preferences, and terms of the Company’s Series A redeemable convertible preferred stock, the Series B, and the Series B-1 (“Preferred Stock”):

Rank

The Preferred Stock ranks senior to common stock as to payment of dividends, distributions of assets upon a liquidation event, or otherwise.

Dividends

The holders of Preferred Stock are entitled to receive non-cumulative dividends, when and if declared by the Board, and in preference to any declaration or payment of any dividend on the Company's common stock at the rate of 8% of the original issue price per share. No dividends have been declared to date.

Voting Rights

Each share of Preferred Stock entitles the holder to one vote on all matters for which shares of common stock may vote. The Series A holders can elect two board members if a minimum of 276,059 shares of Series A are outstanding. If the number of Series A holders falls below 276,059 but not below 110,423 then they can elect one board member. The Series B-1 holders can elect two board members if a minimum of 329,991 shares of Series B-1 are outstanding. The Series B holders vote for remaining board members as a single class with all other shareholders on an "as converted" basis.

Liquidation Preference

In the event of a liquidation, dissolution, or winding up of the Company, or in the event the Company merges with or is acquired by another entity, each holder has a liquidation preference. Liquidating distributions will first be made to holders of shares of Series B-1 at $62.88051 per share and then to holders of Series B and Series A on a pari passu basis at $62.88051 and $62.475 per share, respectively. As the redemption event is outside of our control, all shares of preferred stock have been presented outside of permanent equity. We have also concluded that since the shares of preferred stock are not mandatorily redeemable, but rather are only contingently redeemable, and given that the redemption event is not certain to occur, the shares have not been accounted for as a liability in any of the periods presented.

After all liquidation preferences are fulfilled, the remaining funds and assets of the Company will be distributed between Series B-1 holders and common shareholders ratably based on the number of shares held by common shareholders and the common shares that would be held by Series B-1 holders on an "as converted" basis. If the total amount received by Series B-1 holders is greater than three times the original issue price, than the holders of the Series B-1 are entitled to the greater of three times the original issue price or the amount such holder would have received if all shares of Series B-1 had been converted into common stock immediately prior to such liquidation.

Conversion

Each share of Preferred Stock is convertible into common stock at any time at the option of the holder at a conversion price then in effect and equal to one-for-6.85 subject to adjustment. All outstanding Preferred Stock will automatically convert into common stock at the conversion price then in effect upon a qualified initial public offering of common stock with a public offering price of at least $9.17964 per share and aggregate gross proceeds of at least $50.0 million. All shares of Preferred Stock are convertible into common stock upon the affirmative election of the holders of at least a 65% of the outstanding shares of Preferred Stock. As disclosed in 'Note 10', on October 14, 2020, the Company completed the initial public offering (IPO) of its common stock pursuant to a Registration Statement on Form S-1. As a result, all Preferred Stock was converted into common stock as of the date of the initial public offering.

Redemption

The Preferred Stock allows the holders to redeem their shares upon a change in control in the Company. As a result, the Company classifies the Preferred Stock as mezzanine equity. The Company charges specific incremental issuance costs incurred in the offering of the Preferred Stock against the gross proceeds of the Preferred Stock.

7. Stock-Based Compensation

In 2016, the Company adopted and subsequently amended the 2016 Stock Incentive Plan (the "Plan"). The total number of shares authorized under the Plan as of September 30, 2020 was 3,819,786, and 335,403 shares remain available for future grants as of September 30, 2020. The Plan permits the granting of options and restricted stock. The terms of the agreements are determined by the Company's Board of Directors. The Company's awards vest based on the terms in the agreements and generally vest over four years and have a term of 10 years.

The Company measures employee and non-employee stock-based awards at grant-date fair value and records compensation expense on a straight-line basis over the vesting period of the award. The Company recorded stock-based compensation expense in the following expense categories of its accompanying unaudited interim statements of operations and comprehensive loss (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2020	2019	2020	2019
Research and development	$ 159	$ 93	$ 350	$ 151
General and administrative	153	50	279	146
	$ 312	$ 143	$ 629	$ 297

The following table summarizes option activity under the Stock Plan:

	Options	Weighted average exercise price	Weighted average remaining contract life
Balance at January 1, 2020	1,615,375	$2.60	
Granted	1,116,966	$5.28	
Exercised	(163,292)	$1.28	
Forfeited	(30,824)	$2.95	
Outstanding at September 30, 2020	2,538,225	$3.86	8.95
Vested and expected to vest September 30, 2020	2,485,746	$3.85	8.94
Exercisable at September 30, 2020	684,910	$2.60	8.03

Options granted during the nine months ended September 30, 2020 had a weighted-average grant-date fair value of $3.36. As of September 30, 2020, unrecognized compensation cost for options issued was $4.5 million, and will be recognized over an estimated weighted-average amortization period of 2.88 years. The aggregate intrinsic value of options outstanding and exercisable as of September 30, 2020 was $8.5 million.

The fair value of each option is estimated on the date of grant using a Black-Scholes option pricing model which takes into account inputs such as the exercise price, the estimated fair value of the underlying common stock at grant date, expected term, expected stock price volatility, risk-free interest rate, and dividend yield. The fair value of each grant of stock options was determined by the Company using the methods and assumptions discussed below. Certain of these inputs are subjective and generally required judgement to determine.

- The expected term of employee stock options with service-based vesting is determined using the “simplified” method, whereby the expected life equals the arithmetic average of the vesting term and the original contractual term of the option due to the Company’s lack of sufficient historical data. The expected term of non-employee options is equal to the contractual term.
- The expected stock price volatility is based on historical volatilities of comparable public entities within the Company’s industry.
- The risk-free interest rate is based on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the respective expected term or contractual term.
- The expected dividend yield is 0% because the Company has not historically paid, and does not expect, for the foreseeable future, to pay a dividend on its common stock.
- As the Company’s common stock has not been publicly traded, its board of directors periodically estimated the fair value of the Company’s common stock considering, among other things, contemporaneous valuations of its common stock prepared by an unrelated third-party valuation firm.

The grant date fair value of each option grant was estimated throughout the nine months ended September 30, 2020 using the Black-Scholes option-pricing model using the following weighted-average assumptions:

Expected term	5.91
Expected volatility	74.21%
Risk-free interest rate	0.47%
Expected dividends	—
Fair value of common stock	$5.28

For accounting purposes, restricted shares granted are considered the issuance of shares as opposed to the sale of stock and as such, the Company has recognized compensation expense for these awards. Twenty-five percent of the shares became vested after one year and the remaining shares vest monthly over 36 months so long as the grantee remains employed by or provides service to the Company. In the event the grantee ceases to provide service, the Company has the option to repurchase any or all of the unvested shares at the original issuance price. The following table summarizes the activity relating to these shares for the nine months ended September 30, 2020 :

	Awards
Balance at January 1, 2020	31,900
Vested	15,111
Outstanding at September 30, 2020	16,789

8. Collaboration Agreement—Related Party

In August 2017, the Company entered into a Collaboration agreement with Takeda related to the development of certain ARC molecules as amended in April 2018, October 2018 and March 2020, (the “Collaboration Agreement”). Under the Collaboration Agreement, the Company is responsible to use its commercially reasonable efforts to further research and develop six molecules in accordance with specified development plans for each molecule. Two Designated Molecules, SL-279252 (“DM1”) and SL-115154 (“DM2”) (collectively referred to as the “DMs”), will be progressed through a Phase 1 clinical trial and four Selected Molecules will be developed through the completion of toxicology studies (collectively known as “SMs”). Takeda has an option, which extends through the end of the development term for each molecule, to exclusively license (on a molecule-by-molecule basis) each DM and up to two SMs, which license would grant Takeda exclusive rights to undertake further clinical development and commercialization of the licensed molecule. Additionally, Takeda was granted a right of first negotiation (“ROFN”) to enter into a license for each molecule within a specified class of ARC molecules.

The Company received payments of $8.5 million and $12.1 million in the periods ended September 30, 2019 and 2020, respectively, and recognized total revenue of $50.6 million through September 30, 2020 under the Collaboration Agreement. The Company assessed this arrangement in accordance with ASC 606 and concluded that the Collaboration Agreement had four distinct performance obligations representing the combination of research and development services and participation in a joint development committee associated with both DMs, one SM and the remaining three SMs as a group. The Company also concluded that since the option for the exclusive license was deemed to be at standalone selling price it does not provide the customer with a material right and therefore, it does not represent a separate performance obligation. Finally the Company noted that the ROFN does not guarantee that Takeda can negotiate a license for molecules at prices that are below their respective standalone selling prices and further noted that if Takeda exercises the ROFN, the license fee will be negotiated at standalone selling price for each molecule.

On March 31, 2020, the Company and Takeda entered into an amendment to the Collaboration Agreement (Amendment No. 3) which provided for a second dose expansion cohort for DM1, improvements to the DM1 process and manufacturing controls, certain administrative tasks and a non-refundable up-front payment applied to the license fee for DM1 of $11.3 million. The Company can receive reimbursement for costs incurred in the performance of the second dose expansion cohort up to $3.2 million, plus fifty percent of out-of-pocket costs incurred by the Company for clinical trial materials for the first and second dose expansion cohorts up to $4.0

million and reimbursements of up to $1.6 million for costs related to improvement to the DM1 process and manufacturing controls.

The Company evaluated the consideration anticipated to be received for each performance obligation under Amendment No. 3 and determined that the contractual amounts for each obligation represent the stand-alone selling price and relate directly to the efforts that the Company will exert to fulfill its performance obligation.

The potential reimbursements for costs incurred in the performance of the second dose expansion cohort and costs incurred by the Company for clinical trial materials for the second dose expansion cohort were determined to be variable consideration. The Company determined that the potential reimbursement associated with the second dose expansion cohort was fully constrained and did not include it in the transaction price. The Company anticipates that the reimbursements associated with clinical trial materials will be earned and as such, the amount was included in the transaction price.

The Company further evaluated the terms of Amendment No. 3 to determine if they represented a modification to the existing agreement or a new agreement. The Company determined that improvements to the DM1 process and manufacturing controls are new and distinct performance obligations with underlying revenue that is to be recorded prospectively. The second dose expansion cohort was determined to be a continuation of research and development services being performed. As such, the second dose expansion cohorts represent a modification to the existing agreement and a continuation under the existing research and development performance obligation.

At the outset of the contract with Takeda the Company viewed the option to license molecules as a discrete performance obligation which would be transferred upon Takeda executing their option and remitting consideration that was negotiated and believed to be in line with the stand-alone value of the option. In conjunction with Amendment No. 3, the $11.3 million payment was applied to the license fee and as such, results in a lower cost to license the molecule. The Company evaluated and determined the prepayment provided a material right. Management determined the stand-alone selling price of the material right using comparable arrangements and probability that Takeda will exercise its option to license. The non-refundable payment was recognized as deferred revenue upon receipt of the up-front payment and will be recognized as revenue upon Takeda entering into the underlying license agreement or when it is certain that Takeda will not exercise its option.

The Company recognizes revenue for the allocated upfront payments using a cost-based input measure. In applying the cost-based input method of revenue recognition, the Company uses actual costs incurred relative to budgeted costs expected to be incurred for the combined performance obligation. Revenue is recognized based on actual costs incurred as a percentage of total budgeted costs as the Company completes its performance obligation over the estimated service period. The Company recognizes revenue related to the reimbursable cost as they are incurred.

The stated development term under the Collaboration Agreement commenced on August 8, 2017 and terminates 90 days after the Phase 1 clinical report is delivered to Takeda for each of the DMs. The development term for the SMs expired in the second quarter of 2019 as the toxicology reports for the SMs were delivered to Takeda and the option period for the exclusive license expired.

Revenue recognized under this agreement is related-party revenue.

9. Related-Party Transactions

Takeda had a seat on the Company’s Board of Directors and held an approximate 7.5% ownership interest in the Company’s outstanding shares as of September 30, 2020. As of December 31, 2019, Takeda held an approximate 14% ownership interest in the Company’s outstanding shares. As a result, all revenue, and deferred revenue associated with the Takeda Collaboration Agreement are represented as related-party transactions. Prepaids and other current assets includes $2.4 million of cost that are reimbursable by Takeda under the Collaboration Agreement. Following the completion of the Company's initial public offering in October 2020, Takeda no longer has a seat on the Company's Board of Directors.

10. Subsequent Events

The Company has evaluated subsequent events from the balance sheet date through November 13, 2020, the date at which the financial statements were available to be issued, and there are no other items requiring disclosure except for the following:

Stock Split

In September 2020, the Board of Directors and the stockholders of the Company approved a 6.85-for-1 stock split of the Company's outstanding common stock and adjusted the conversion ratio of the Company's preferred stock accordingly. The forward stock split was effective as of October 1, 2020. All common stock, preferred stock, and per share information has been retroactively adjusted to give effect to this forward stock split and the adjusted conversion ratios for all periods presented. Shares of common stock underlying outstanding stock options and other equity instruments were proportionately increased and the respective per share value and exercise prices, if applicable, were proportionately decreased in accordance with the terms of the agreements governing such securities. There were no changes in the par values of the Company's common stock and preferred stock as a result of the forward stock split.

Initial Public Offering

On October 14, 2020, the Company completed the initial public offering ("IPO") of its common stock pursuant to a Registration Statement on Form S-1. In the IPO, the Company sold an aggregate of 13,664,704 shares of common stock (including 1,782,352 shares issued pursuant to the underwriters' option to purchase additional shares) under the Registration Statement at a public offering price of $17.00 per share. On October 14, 2020 the Company received net proceeds of approximately $213.5 million, after deducting underwriting discounts and commissions of $16.3 million and offering expenses of $2.5 million. Upon the completion of the IPO, all outstanding shares of the Company's Preferred Stock were converted into 20,300,253 shares of common stock.

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

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our unaudited condensed consolidated financial statements and related notes included in Part I, Item 1 of this Quarterly Report on Form 10-Q, or this Quarterly Report, as well as the audited consolidated financial statements and notes and Management's Discussion and Analysis of Financial Condition and Results of Operations, included in our Prospectus dated October 8, 2020 filed with the SEC pursuant to Rule 424(b)(4), which we refer to as the "Prospectus". This discussion and other parts of this Quarterly Report contain forward-looking statements that involve risks 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". You should carefully read the "Special Note Regarding Forward-Looking Statements" and "Risk Factors" sections of this Quarterly Report to gain an understanding of the important factors that could cause actual results to differ materially from the results described below.

Overview

We are an innovative clinical-stage biotechnology company pioneering the development of dual-sided fusion proteins as an entirely new class of biologic medicine. We believe our approach has the potential to fundamentally transform the therapeutic modulation of the immune system. We have created a novel approach to immune-modulation by designing biologics with structural characteristics that are not achievable by existing therapeutic modalities. Compounds derived from our proprietary Agonist Redirected Checkpoint, or ARC®, platform simultaneously inhibit checkpoint molecules and activate costimulatory molecules within a single therapeutic. Our initial product candidates are designed to be differentiated therapeutics addressing molecular targets that are well characterized and scientifically validated in immuno-oncology but are underexploited by current treatment modalities.

Our lead, wholly owned product candidate, SL-172154, has been rationally designed to simultaneously inhibit the CD47/SIRPα checkpoint interaction to restore an anti-tumor immune response and to activate the CD40 costimulatory receptor to bolster an immune response. We are currently conducting a Phase 1 clinical trial evaluating SL-172154 in patients with ovarian cancer, and we expect to announce initial data from the dose-escalation portion of this trial in the second half of 2021. We plan to initiate a second Phase 1 trial evaluating SL-172154 in patients with cutaneous squamous cell carcinoma or head and neck squamous cell carcinoma, and we expect to announce data from the dose-escalation portion of this trial in the second half of 2022. Our second product candidate, SL-279252, which is being developed in collaboration with Takeda, has been rationally designed to simultaneously inhibit the PD-1/PD-L1 interaction and activate the OX40 receptor. We are evaluating SL-279252 in a Phase 1 clinical trial in patients with advanced solid tumors and lymphoma, and we expect to announce data from the dose-escalation portion of this trial in the second half of 2021. In addition to our clinical-stage ARC product candidates, we possess a deep pipeline of preclinical immuno-oncology product candidates. Longer-term, we are pursuing additional disease areas, including autoimmune diseases, where our dual-sided fusion protein platforms may provide advantages over current treatment modalities.

Since our inception in 2016, we have devoted substantially all of our resources to developing and perfecting our intellectual property rights, conducting research and development activities, including undertaking preclinical studies of our product candidates, conducting clinical trials of our most advanced product candidates, manufacturing our product candidates, organizing and staffing our company, business planning, and raising capital. We do not have any products approved for sale, and we have not generated any revenue from product sales. We continue to have related party revenue under a collaboration agreement with Takeda. We have funded our operations as of the filing date of this quarterly report through the proceeds of our initial public offering for approximately $213.5 million (subsequent to September 30, 2020 and not reflected in financial statements), the sale of redeemable convertible preferred stock for approximately $152.9 million, the issuance of convertible notes for approximately $10.5 million and payments received pursuant to our collaboration agreement with Takeda for approximately $76.5 million.

For the nine months ended September 30, 2020 and 2019, our net loss was $24.6 million and $16.6 million, respectively. We have not been profitable since inception, and as of September 30, 2020, we had an accumulated

deficit of $60.1 million and $134.9 million in cash and cash equivalents and short-term investments. We expect to continue to incur significant expenses and increasing operating losses in the near term. We expect our expenses will increase substantially in connection with our ongoing activities, as we:

- continue to advance the preclinical and clinical development of our lead product candidates;
- initiate preclinical studies and clinical trials for additional product candidates that we may identify in the future;
- expand our operational, financial, and management systems and increase personnel, including personnel to support our clinical development, manufacturing, and commercialization efforts;
- continue to develop, perfect, and defend our intellectual property portfolio; and
- incur additional legal, accounting, or other expenses in operating our business, including the additional costs associated with operating as a public company.

We do not expect to generate significant product revenue unless and until we successfully complete development and obtain regulatory and marketing approval of, and begin to sell, one or more of our product candidates, which we expect will take several years. We expect to spend a significant amount in development and marketing costs prior to such time. We may never succeed in achieving regulatory and marketing approval for our product candidates. We may obtain unexpected results from our preclinical and clinical trials. We may elect to discontinue, delay, or modify preclinical and clinical trials of our product candidates. A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. Accordingly, until such time as we can generate significant product revenue, if ever, we expect to continue to seek private or public equity and debt financing to meet our capital requirements. There can be no assurance that such funding may be available to us on acceptable terms, or at all, or that we will be able to commercialize our product candidates. In addition, we may not be profitable even if we commercialize any of our product candidates.

Coronavirus Pandemic

On March 10, 2020, the World Health Organization characterized the novel COVID-19 virus as a global pandemic. There is significant uncertainty as to the effects of this disease which may, among other things, materially impact our business, including our ongoing and planned clinical trials. To date, we have experienced delays in our SL-279252 and SL-172154 clinical trials as a result of the ongoing pandemic, including delays with certain third-party vendors supporting this trial. We temporarily paused enrollment of patients for our clinical trial of SL-279252 between March and May 2020, and we resumed enrollment in June 2020. As “shelter in place” orders and other public health guidance measures are reinstated in the locations of our clinical trial sites, we expect that some patients may also choose to forego one or more doses in our clinical trials, due to challenges faced by such patients in travelling to our clinical trial sites, which may negatively affect the study results. We expect that our clinical development program timelines will continue to be negatively affected by COVID-19, although the degree of these delays is difficult to predict. Further, due to “shelter in place” orders and other public health guidance measures, we may be required to implement a work-from-home policy for all staff members excluding those necessary to maintain minimum basic operations. In such an instance, our increased reliance on personnel working from home may negatively impact productivity, or disrupt, delay, or otherwise adversely impact our business. For example, with our personnel working from home, some of our research activities that require our personnel to be in our laboratories may be delayed.

Due to the impact of the COVID-19 pandemic and work-from-home policies and other operational limitations mandated by federal, state, and local governments as a result of the pandemic, certain of our research and development activities, including the conduct of preclinical studies, have been delayed and may be further delayed and other aspects of our business, such as the conduct of various corporate functions and the ability of our Board and management to provide oversight and guidance may be adversely impacted until such operational limitations are lifted. The COVID-19 pandemic or local outbreaks associated with the COVID-19 pandemic could result in difficulty manufacturing our product candidates, securing clinical trial site locations, CROs, and/or trial monitors and other critical vendors and consultants supporting our clinical trials. In addition, outbreaks or the perception of an

outbreak near a clinical trial site location could impact our ability to enroll patients or to complete all scheduled physician visits for currently enrolled patients. These situations, or others associated with COVID-19 pandemic, could cause delays in our clinical trial plans and could increase expected costs, all of which could have a material adverse effect on our business and its financial condition. At the current time, we are unable to quantify the potential effects of the COVID-19 pandemic on our future operations.

Collaboration and License Agreements

Collaboration Agreement with Takeda

On August 8, 2017, we entered into a Collaboration Agreement with Millennium Pharmaceuticals, Inc., or Takeda, a wholly owned subsidiary of Takeda Pharmaceutical Company, Ltd., or the Collaboration Agreement. The Collaboration Agreement was subsequently amended in April 2018, October 2018, and March 2020.

Pursuant to the Collaboration Agreement, we are required to use our commercially reasonable efforts to conduct preclinical and Phase 1 clinical trials for two molecules, SL-279252 and SL-115154, and Takeda has an exclusive option to license one or both of these clinical-stage ARC molecules for a specified amount of time up to and following the conclusion of each respective Phase 1 trial. While we are currently evaluating SL-279252 in a Phase 1 clinical trial, we have not yet conducted a Phase 1 clinical trial for SL-115154. During the development phase of the Collaboration Agreement, we may not, by ourselves or through a third party, develop or commercialize a compound, molecule or product that targets both PD-1 and OX40L, or a compound, molecule or product that targets both CSF1R and CD40L.

Further, pursuant to the Collaboration Agreement, we agreed to conduct certain preclinical studies on four additional preclinical ARC molecules, and Takeda had an option to license up to two of the four preclinical molecules. We completed our research and development activities related to the four preclinical molecules and delivered a final report to Takeda. Takeda elected to not exercise its option to enter into up to two licenses for such molecules, and Takeda's option period for such molecules has now lapsed. As a result, the Collaboration Agreement is terminated as to the four preclinical molecules and Takeda does not have any rights to participate in the development or commercialization of such molecules.

Under the Collaboration Agreement, Takeda is granted a right of first negotiation to enter into licenses for each molecule within a specified class of ARC molecules. To exercise its right of first negotiation, Takeda will be required to provide a notice within a specified time, and if the parties do not conclude a license agreement within a set timeframe, we will be entitled to enter into licenses with third parties, subject to certain conditions.

Thus far under the Collaboration Agreement, we have received approximately $76.5 million in option payments, milestone payments, and expense reimbursements from Takeda. If Takeda exercises its exclusive option to license one or both of the clinical-stage ARC molecules (SL-279252 and SL-115154), we will enter into a license agreement with Takeda with respect to such compound. Any such license agreement would, among other things, require Takeda to use its commercially reasonable efforts to develop the licensed compound and seek approval for the compound. In addition, Takeda would be solely responsible, at its costs, for the development, manufacture, and commercialization of the licensed ARC molecules. If both ARC molecules are licensed, we would be entitled to additional payments consisting of up to an aggregate of $78.8 million in license fee payments and up to an aggregate of $450 million in clinical, regulatory, and sales milestone payments. In addition, we would be eligible for tiered royalty payments on net sales of licensed products at percentages ranging from the high single digits to sub-teens, subject to specified reductions, during the royalty term.

If Takeda exercises its option to enter into a license agreement, the royalty term with respect to the licensed product would extend, on a country-by-country basis, from the period commencing on the first commercial sale of the product in such country and ending on the later of (i) the expiration of the last to expire of the valid claims of the applicable licensed patent rights covering the product in such country or (ii) the tenth anniversary of the first commercial sale of the product in such country.

Unless sooner terminated, the Collaboration Agreement will continue until the later of (a) February 8, 2021, (b) the earlier of (i) the 90th day following delivery of a report detailing certain results of the SL-279252 Phase 1 clinical trial and (ii) the exercise by Takeda of its right to an exclusive license with respect to SL-279252, and (c) the earlier of (i) the 90th day following delivery of a report detailing certain results of the SL-115154 Phase 1 clinical

trial and (ii) the exercise by Takeda of its right to an exclusive license with respect to SL-115154. Either party may terminate the Collaboration Agreement prior to expiration upon the insolvency or uncured material breach of the other party.

Heat License Agreement

In June 2016, we entered into an Exclusive License Agreement, or the Heat License Agreement, with Heat Biologics Inc., or Heat. The Heat License Agreement was subsequently amended in November 2016, December 2016, and March 2017. Pursuant to the Heat License Agreement, Heat granted to us a worldwide, sublicensable exclusive license to research, develop, manufacture, and commercialize products under three provisional patent applications, including all patents issuing from such applications, or the Fusion Protein Patent Rights and a worldwide, sublicensable nonexclusive license to research, develop, manufacture, and commercialize certain know how owned and controlled by Heat related to the Fusion Protein Patent Rights.

Under the Heat License Agreement, Heat was required to conduct certain research and development services under a mutually-agreed upon research and development plan and Heat was eligible to receive financial support from us for these efforts. Effective March 2017, Heat completed all research and development services under the Heat License Agreement and assigned to us three patent applications and all data derived from the research and development activities, referred to collectively as the Research Services Inventions. Pursuant to the terms of the Heat License Agreement, we are obligated to use commercially reasonable efforts to diligently research and develop at least one product covered by the Fusion Protein Patent Rights, including the obligation to file an IND application for such product. Our development efforts, including the development of SL-279252 and certain other ARC compounds, to date satisfy these obligations. In addition, we are to provide annual reports to Heat on or before the anniversary of the effective date of the Heat License Agreement to inform Heat of our progress.

Unless sooner terminated or extended, the term of the Heat License Agreement continues until the later of 20 years following the effective date and the expiration of the last-to-expire royalty term. Either party may terminate the agreement due to a material breach by the other party (subject to a 90-day cure period) or if the other party files for bankruptcy. In the event we terminate the Heat License Agreement due to a material breach by Heat, Heat must assign to us all right, title, and interest in the patent rights licensed under the Heat License Agreement.

In addition to an upfront payment of $50,000, the Heat License Agreement requires us to make further payments to Heat of up to $20.6 million in the aggregate, for the achievement of specified development, regulatory, and commercial sale milestones for certain licensed products. We are also required to pay Heat a percentage of certain upfront fees or other non-royalty payments we receive that are not tied to milestone events under any sublicense of the Fusion Protein Patent Rights. We are also required to pay Heat a royalty on all worldwide net sales by us, our affiliates, and sublicenses of certain licensed products in the low single digits. Royalties are payable, on a product-by-product and country-by-country basis, commencing on the first commercial sale of such product and continuing until the last-to-expire valid patent claim to the licensed patent rights that cover such product in that country.

Components of our Results of Operation

Collaboration Revenue – Related Party

Pursuant to the Collaboration Agreement, we are eligible to receive up to $33.8 million if Takeda exercises options to enter into license agreements for SL-279252 and $45.0 million if Takeda exercises options to enter into license agreements for SL-115154. We are also entitled to receive reimbursements for certain materials and costs incurred in conjunction with research and development activities. We are further eligible to receive up to $450.0 million in additional fees if certain milestones are reached, and we are eligible to receive tiered royalties from the high single digits to the sub teens percentages based on annual worldwide net sales.

We received $12.1 million for the nine months ended September 30, 2020. We have recognized total revenue of $50.6 million through September 30, 2020 under the Collaboration Agreement.

We have no products approved for commercial sale, and we have not generated any revenue from commercial product sales. Our total revenue to date has been generated solely from our Collaboration Agreement with Takeda. We expect to continue to recognize revenue under this agreement as development work is performed. We expect that any collaboration revenue we generate from our collaboration agreement with Takeda and any future collaboration

partners will fluctuate from period to period as a result of the timing and the amount of milestones and other payments.

Operating Expense

Research and Development

Our research and development expenses consist primarily of costs incurred in connection with the discovery and development of our product candidates. These expenses include:

- expenses incurred under agreements with contract research organizations, or CROs, as well as investigative sites and consultants that conduct our preclinical studies and clinical trials;
- manufacturing and development expenses and the costs of acquiring and manufacturing preclinical study and clinical trial materials;
- analysis of manufacturing processes for optimization;
- employee-related expenses, including salaries, benefits, and stock-based compensation;
- fees paid to consultants who assist with research and development activities;
- expenses relating to regulatory activities, including filing fees paid to regulatory agencies;
- laboratory materials and supplies used to support our research activities; and
- allocated expenses for facility-related costs.

The following table summarizes our research and development expenses by product candidate:

(in thousands)	Nine months ended September 30, 2020	2019
	(unaudited)	
SL-172154	$ 5,082	$ 6,018
SL-279252	12,080	5,207
Other pipeline candidates	4,408	4,560
Internal costs, including personnel related benefits, facilities, and depreciation	6,126	4,662
	$ 27,696	$ 20,447

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect our research and development expenses to increase significantly over the next several years as we conduct preclinical studies and clinical trials, including later-stage clinical trials, for our current and future product candidates and pursue regulatory approval of our product candidates, including preparing regulatory filings. As we expand our research and development activities, we will correspondingly incur an increase in personnel costs, including salaries, employee benefits, and stock-based compensation, as discussed in greater detail below under “General and Administrative Expenses.”

The process of conducting the necessary preclinical and clinical research to obtain regulatory approval is costly and time consuming. The actual probability of success for our product candidates may be affected by a variety of factors including:

- the safety and efficacy of our product candidates;
- early clinical data for our product candidates;

- investment in our clinical programs;
- the ability of collaborators to successfully develop our licensed product candidates;
- competition;
- manufacturing capability; and
- commercial viability.

We may never succeed in achieving regulatory approval for any of our product candidates. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of our product candidates, if ever.

General and Administrative Expense

General and administrative expense consists primarily of personnel expenses, including salaries, benefits, and stock-based compensation expense, for employees and consultants in executive, finance, accounting, legal, and human resource functions. General and administrative expense also includes corporate facility costs, including rent, utilities, depreciation, and maintenance, not otherwise included in research and development expense, as well as legal fees related to intellectual property and corporate matters and fees for accounting and consulting services.

We expect that our general and administrative expense will increase in the future to support our continued research and development activities and as a result of the increased costs of operating as a public company. These increases will likely include increased costs related to the hiring of additional personnel and fees to outside consultants, lawyers, and accountants, among other expenses. Additionally, we anticipate increased costs associated with being a public company, including expenses related to services associated with maintaining compliance with the requirements of Nasdaq and the SEC, insurance, and investor relations costs. If any of our current or future product candidates obtains U.S. regulatory approval, we expect that we would incur significantly increased expenses associated with building a sales and marketing team.

Interest Income

Interest income consists of interest earned on our cash, cash equivalents and short-term investments, which consists of amounts held in a money market fund and at various times in short-term government obligations.

Income Taxes

Since our inception, we have not recorded any income tax benefits for the net operating losses, or NOLs, we have incurred and for our research and development tax credits, as we believe, based upon the weight of available evidence, that it is more likely than not that all of our NOLs and tax credits will not be realized. Our NOLs and tax credit carryforwards will begin to expire in 2036. We have recorded a full valuation allowance against our deferred tax assets at each balance sheet date.

Results of Operations

Comparison of the Three Months Ended September 30, 2020 and 2019

The following table sets forth our results of operations for the three months ended September 30, 2020 and 2019.

(in thousands)	Three Months Ended September 30,		Change	
	2020	2019	Dollar	Percentage
	(unaudited)			
Collaboration revenue – related party	$ 2,435	$ 1,784	$ 651	36.5 %
Operating expenses:				
Research and development	11,804	7,945	3,859	48.6 %
General and administrative	2,470	1,366	1,104	80.8 %
Loss from operations	(11,839)	(7,527)	(4,312)	57.3 %
Other income (expense):				
Interest income	86	279	(193)	(69.2)%
Other	(76)	(31)	(45)	145.2 %
Net loss	$ (11,829)	$ (7,279)	$ (4,550)	62.5 %

Collaboration Revenue – Related Party

Collaboration revenue increased by $0.7 million, or 36.5%, to $2.4 million for the three months ended September 30, 2020 from $1.8 million for the three months ended September 30, 2019. The increase was primarily driven by increased clinical and development work on SL-279252 associated with the Collaboration Agreement.

Research and Development Expense

Research and development expenses increased by $3.9 million, or 48.6%, to $11.8 million for the three months ended September 30, 2020 from $7.9 million for the three months ended September 30, 2019. The increase was primarily attributable to an increase of $3.5 million in manufacturing and clinical costs in connection with SL-279252 and SL-172154, an increase in personnel, facilities, and clinical related costs of $.9 million as a result of an increase in headcount and expansion of our manufacturing and clinical development capabilities and an increase in pharmacology and laboratory related costs of $.4 million offset by a $.9 million decrease in nonclinical costs as a result of completing nonclinical studies for SL-172154 in 2019.

General and Administrative Expense

General and administrative expenses increased by $1.1 million, or 80.8%, to $2.5 million for the three months ended September 30, 2020 from $1.4 million for the three months ended September 30, 2019. The increase was primarily due to a $1.1 million increase in personnel-related costs driven by higher employee headcount and compensation resulting from transitioning consultants to full-time employee positions.

Interest Income

Interest income decreased by $0.2 million to $0.1 million for the three months ended September 30, 2020 from $0.3 million for the three months ended September 30, 2019. The decrease was primarily due to a decrease in short-term investments in corporate and government obligations in 2020 compared to 2019.

Results of Operations

Comparison of the Nine Months Ended September 30, 2020 and 2019

The following table sets forth our results of operations for the nine months ended September 30, 2020 and 2019.

(in thousands)	Nine Months Ended September 30,		Change	
	2020	2019	Dollar	Percentage
	(unaudited)			
Collaboration revenue – related party	$ 8,592	$ 7,066	$ 1,526	21.6 %
Operating expenses:				
Research and development	27,696	20,447	7,249	35.5 %
General and administrative	5,816	4,062	1,754	43.2 %
Loss from operations	(24,920)	(17,443)	(7,477)	42.9 %
Other income (expense):				
Interest income	474	902	(428)	(47.5)%
Other	(145)	(72)	(73)	101.4 %
Net loss	$ (24,591)	$ (16,613)	$ (7,978)	48.0 %

Collaboration Revenue – Related Party

Collaboration revenue increased by $1.5 million, or 21.6%, to $8.6 million for the nine months ended September 30, 2020 from $7.1 million for the nine months ended September 30, 2019. The increase was primarily driven by increased clinical and development work on SL-279252 associated with the Collaboration Agreement.

Research and Development Expense

Research and development expenses increased by $7.2 million, or 35.5%, to $27.7 million for the nine months ended September 30, 2020 from $20.4 million for the nine months ended September 30, 2019. The increase was primarily attributable to an increase of $7.4 million in manufacturing and clinical costs in connection with SL-279252 and SL-172154 and an increase in personnel cost of $1.2 million as a result of an increase in headcount to expand our manufacturing and clinical development capabilities offset by a decrease of $1.4 million in nonclinical studies as a result of completing nonclinical studies for SL-172154 in 2019.

General and Administrative Expense

General and administrative expenses increased by $1.8 million, or 43.2%, to $5.8 million for the nine months ended September 30, 2020 from $4.1 million for the nine months ended September 30, 2019. The increase was primarily due to a $1.3 million increase in personnel-related costs driven by higher employee headcount and compensation resulting from transitioning consultants to full-time employee position.

Interest Income

Interest income decreased by $0.4 million to $0.5 million for the nine months ended September 30, 2020 from $0.9 million for the nine months ended September 30, 2019. The decrease was primarily due to a decrease in short-term investments in corporate and government obligations in 2020 compared to 2019.

Liquidity and Capital Resources

Since our inception, our primary sources of liquidity have been generated through our Collaboration Agreement with Takeda and by sales of our preferred stock and common stock, including our initial public offering. As of September 30, 2020, we had an accumulated deficit of $60.1 million and $134.9 million of cash and cash equivalents and short-term investments. On October 14, 2020, as a result of our initial public offering, we received net proceeds of approximately $213.5 million. We anticipate incurring additional losses and negative cash flows from operations until such time, if ever, that we can generate significant sales of our product candidates currently in development. We intend to raise additional capital through equity offerings and/or debt financings or from other potential sources of liquidity, which may include new collaborations, licensing or other commercial agreements for

one or more of our development programs or patent portfolios. Our ability to fund planned clinical operations, research and development, and commercialization of product candidates is expected to depend on the amount and timing of cash receipts from these funding sources. Adequate additional funding may not be available to the us on acceptable terms, or at all. The failure to raise funds as and when needed could have a negative impact on our financial condition and ability to pursue its business strategies.

Capital Resources and Funding Requirements

Our primary uses of cash are to fund our operations, which consist primarily of research and development expenditures related to our programs, product development costs, operating expenses, and working capital requirements. We believe that our cash and cash equivalents and short-term investments, together with the net proceeds from our initial public offering, will enable us to fund our operating expenses through the end of 2024. We expect to incur substantial additional expenditures in the near term to support our ongoing activities including clinical trials of several product candidates. Additionally, we expect to incur additional costs as a result of operating as a public company. We expect to continue to incur net losses for the next several years, and we are highly dependent on our ability to find additional sources of funding in the form of debt, equity financing, or additional partnerships. Our ability to fund our product development and clinical operations will depend on the amount and timing of cash received from planned financings. Our future capital requirements will depend on many factors, including:

- the scope, timing, progress, and results of discovery, preclinical development, laboratory testing, and clinical trials for our product candidates;
- the costs of manufacturing our product candidates for clinical trials and in preparation for marketing approval and commercialization;
- the extent to which we enter into collaborations or other arrangements with additional third parties in order to further develop our product candidates;
- the costs of preparing, filing, and prosecuting patent applications, maintaining, and enforcing our intellectual property rights and defending other intellectual property-related claims;
- the costs and fees associated with the discovery, acquisition, or in-license of additional product candidates or technologies;
- our ability to establish additional collaborations on favorable terms, if at all;
- the costs required to scale up our clinical, regulatory, and manufacturing capabilities;
- the costs of future commercialization activities, if any, including establishing sales, marketing, manufacturing, distribution, and storage capabilities, for any of our product candidates for which we receive marketing approval; and
- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval.

Until we obtain regulatory approval to market our product candidates, if ever, we cannot generate revenues from sales of our products. Even if we are able to sell our products, we may not generate a sufficient amount of product revenues to finance our cash requirements. Accordingly, we may seek to raise any necessary additional capital through a combination of public or private equity offerings, debt financings, collaborations, licensing arrangements, and other marketing and distribution agreements. There can be no assurance that such funding may be available to us on acceptable terms, or at all. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated preclinical studies and clinical trials. The issuance of equity securities may result in dilution to stockholders. If we raise additional funds through the issuance of debt securities, these securities may have rights, preferences and privileges senior to those of our common stock and the terms of the debt securities could impose significant restrictions on our operations. The

failure to raise funds as and when needed could have a negative impact on our financial condition and ability to pursue our business strategies. Additionally, if additional funding is not secured when required, we may need to delay or curtail our operations until such funding is received, which would have a material adverse impact on our business prospects and results of operations.

Cash Flows

The following table shows a summary of our cash flows for the periods indicated:

(in thousands)	Nine months ended September 30, 2020	2019
	(unaudited)	
Net cash used in operating activities	$ (19,616)	$ (13,354)
Net cash (used in) provided by investing activities	25,166	(3,062)
Net cash provided by financing activities	116,037	—
Net (decrease) increase in cash and cash equivalents	$ 121,587	$ (16,416)

Net Cash Used in Operating Activities

During the nine months ended September 30, 2020, net cash used in operating activities was $19.6 million and primarily reflected our net loss of $24.6 million and a $3.9 million net increase in our operating assets and liabilities, partially offset by noncash charges of $0.6 million in stock-based compensation and $0.4 million in depreciation expense.

During the nine months ended September 30, 2019, net cash used in operating activities was $13.4 million and primarily reflected our net loss of $16.6 million and a $2.6 million net increase in our operating assets and liabilities, partially offset by noncash charges of $0.3 million in stock-based compensation and $0.4 million in depreciation expense.

Net Cash (Used in) Provided by Investing Activities

During the nine months ended September 30, 2020, net cash provided by investing activities was $25.2 million of which $0.5 million was used to purchase property and equipment, $5.6 million was used to purchase short-term investments, and $31.3 million was received from the sale of short-term investments.

During the nine months ended September 30, 2019, net cash used in investing activities was $3.1 million of which $0.4 million was used to purchase property and equipment, $35.3 million was used to purchase short-term investments, and $32.6 million was received from the sale of short-term investments.

Net Cash Provided by Financing Activities

During the nine months ended September 30, 2020, net cash provided by financing activities was $116.0 million and was primarily from the sale of our Series B and B-1 redeemable convertible preferred stock.

Contractual Obligations and Other Commitments

The following table summarizes our contractual obligations and commitments at September 30, 2020:

(in thousands)	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years	Total
Operating lease obligations	$ 519	$ 1,472	$ 1,562	$ 2,743	$ 6,296
Total	$ 519	$ 1,472	$ 1,562	$ 2,743	$ 6,296

The commitment amounts in the table above are associated with contracts that are enforceable and legally binding and that specify all significant terms, including fixed or minimum services to be used, fixed, minimum, or variable price provisions, and the approximate timing of the actions under the contracts. Payments due upon cancellation consisting only of payments for services provided or expenses incurred, including noncancelable obligations of our service providers, up to the date of cancellation are not included in the preceding table as the amount and timing of such payments are not known.

We have not included any potential contingent payments upon the achievement by us of specified regulatory and commercial events, as applicable, or patent prosecution or royalty payments we may be required to make under the Heat License Agreement. We have excluded these potential payments in the contractual obligations table because the timing and likelihood of these contingent payments are not currently known and would be difficult to predict or estimate. See "Collaboration and License Agreements."

Contractual obligations represent future cash commitments and liabilities under agreements with third parties, and exclude contingent liabilities for which we cannot reasonably predict future payment. Our contractual obligations result primarily from obligations for various contract manufacturing organizations and clinical research organizations, which include potential payments we may be required to make under its agreements. The contracts also contain variable costs and milestones that are hard to predict as they are based on such things as patients enrolled and clinical trial sites. The timing of payments and actual amounts paid under contract manufacturing organization, or CMO, and CRO agreements may be different depending on the timing of receipt of goods or services or changes to agreed-upon terms or amounts for some obligations. Also, those agreements are cancellable upon written notice by us and, therefore, not long-term liabilities.

Off-Balance Sheet Arrangements

During the periods presented, we did not have, nor do we currently have, any relationships with unconsolidated entities or financial partnerships, including entities sometimes referred to as structured finance or special purpose entities that were established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. We do not engage in off-balance sheet financing arrangements. In addition, we do not engage in trading activities involving non-exchange traded contracts. We therefore believe that we are not materially exposed to any financing, liquidity, market, or credit risk that could arise if we had engaged in these relationships.

Critical Accounting Policies

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue recognition, the accrual for research and development expenses, and the valuation of stock-based awards. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our financial statements included elsewhere in this Quarterly Report, we believe the following accounting policies are the most critical to the judgments and estimates used in the preparation of our financial statements.

Revenue Recognition

We have and may continue to enter into collaboration agreements with other companies. Arrangements with collaborators may include licenses to intellectual property, research and development services, manufacturing services for clinical and commercial supply, and participation on joint steering and patent committees. We evaluate the promised goods or services in the contract to determine which promises, or group of promises, represent performance obligations. In contemplation of whether a promised good or service meets the criteria required of a performance obligation, we consider the stage of development of the underlying intellectual property, the capabilities and expertise of the customer relative to the underlying intellectual property, and whether the promised goods or services are integral to or dependent on other promises in the contract. When accounting for an arrangement that contains multiple performance obligations, we develop judgmental assumptions, which may include market conditions, reimbursement rates for personnel costs, development timelines, and probabilities of regulatory success to determine the stand-alone selling price for each performance obligation identified in the contract.

When we conclude that a contract should be accounted for as a combined performance obligation and recognized over time, we then determine the period over which revenue should be recognized and the method by which to measure revenue. We generally recognize revenue using a cost-based input method.

We recognize collaboration revenue when our customer or collaborator obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. To determine revenue recognition for such arrangements, we perform the following five steps:

i. identify the contract(s) with a customer;

ii. identify the performance obligations in the contract;

iii. determine the transaction price;

iv. allocate the transaction price to the performance obligations within the contract; and

v. recognize revenue when (or as) the entity satisfies a performance obligation.

We only apply the five-step model to contracts when we determine that it is probable we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer.

At contract inception, we assess the goods or services promised within the contract to determine whether each promised good or service is a performance obligation. The promised goods or services in the arrangement consist of a license to our intellectual property and research, development and manufacturing services. We may provide options to additional items in such arrangements, which are accounted for as separate contracts when the customer elects to exercise such options, unless the option provides a material right to the customer. Performance obligations are promises in a contract to transfer a distinct good or service to the customer that (i) the customer can benefit from on its own or together with other readily available resources, and (ii) is separately identifiable from other promises in the contract. Goods or services that are not individually distinct performance obligations are combined with other promised goods or services until such combined group of promises meet the requirements of a performance obligation.

We determine transaction price based on the amount of consideration we expect to receive for transferring the promised goods or services in the contract. Consideration may be fixed, variable, or a combination of both. At contract inception for arrangements that include variable consideration, we estimate the probability and extent of consideration we expect to receive under the contract utilizing either the most likely amount method or expected amount method, whichever best estimates the amount expected to be received. We then consider any constraints on the variable consideration and include in the transaction price variable consideration to the extent it is deemed probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

We then allocate the transaction price to each performance obligation based on the relative standalone selling price and recognize revenue as the amount of the transaction price that is allocated to the respective performance obligation when (or as) control is transferred to the customer and the performance obligation is satisfied. For performance obligations that consist of licenses and other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

We record amounts as accounts receivable when the right to consideration is deemed unconditional. When consideration is received, or such consideration is unconditionally due, from a customer prior to transferring goods or services to the customer under the terms of a contract, a contract liability is recorded as deferred revenue.

Amounts received prior to satisfying the revenue recognition criteria are recognized as deferred revenue in our balance sheet. Deferred revenues expected to be recognized as revenue within the 12 months following the balance sheet date are classified as a current liability. Deferred revenues not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as noncurrent liabilities.

Research and Development Expense

Research and development expenses consist primarily of costs incurred in connection with the development of our product candidates. We expense research and development costs as incurred.

We accrue an expense for nonclinical studies and clinical trial activities performed by vendors based upon estimates of the proportion of work completed. We determine the estimates by reviewing contracts, vendor agreements and purchase orders, and through discussions with our internal personnel and external service providers as to the progress or stage of completion of trials or services and the agreed-upon fee to be paid for such services. However, actual costs and timing of clinical trials are highly uncertain, subject to risks and may change depending upon a number of factors, including our clinical development plan.

We make estimates of our prepaid and accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known at that time. If the actual timing of the performance of services or the level of effort varies from the estimate, we will adjust the accrual accordingly. Nonrefundable advance payments for goods and services, including fees for process development or manufacturing and distribution of clinical supplies that will be used in future research and development activities, are deferred and recognized as expense in the period that the related goods are consumed or services are performed.

Stock-Based Compensation

We measure compensation expense for all share-based awards based on the estimated fair value of the share-based awards on the grant date. We use the Black-Scholes option pricing model to value our stock option awards. We recognize compensation expense on a straight-line basis over the requisite service period, which is generally the vesting period of the award. We have not issued awards for which vesting is subject to a market or performance conditions.

The Black-Scholes option-pricing model requires the use of subjective assumptions that include the expected stock price volatility and the fair value of the underlying common stock on the date of grant. See Note 7 to our unaudited financial statements included elsewhere in this Quarterly Report for information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock options granted during the nine months ended September 30, 2020.

Recent Accounting Pronouncements

See Note 2 to our financial statements found elsewhere in this Quarterly Report for a description of recent accounting pronouncements applicable to our financial statements.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation and changing prices had a significant impact on our results of operations for any periods presented herein.

JOBS Act Transition Period

We are an emerging growth company as defined in the JOBS Act. Under the JOBS Act, an emerging growth company can take advantage of the extended transition period for complying with new or revised accounting standards and delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption from complying with new or revised accounting standards and, therefore, will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements under the JOBS Act. Subject to certain conditions, as an emerging growth company, we may rely on certain of these exemptions, including without limitation exemptions to the requirements for (1) providing an auditor’s attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (2) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report

providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an emerging growth company until the earlier to occur of (a) the last day of the fiscal year (i) following the fifth anniversary of the completion of our initial public offering, (ii) in which we have total annual gross revenues of at least $1.07 billion or (iii) in which we are deemed to be a "large accelerated filer" under the rules of the SEC, 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 (b) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

We are also a "smaller reporting company," meaning that the market value of our stock held by non-affiliates plus the proposed aggregate amount of gross proceeds to us as a result of our initial public offering is less than $700.0 million and our annual revenue is less than $100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $250.0 million or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700.0 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Item 3. Qualitative and Quantitative Disclosures About Market Risk

Interest Rate Risk

We are exposed to market risk related to changes in interest rates. As of September 30, 2020, we had cash and cash equivalents and short-term investments of $134.9 million consisting of bank deposits, monies in a money market fund and U.S. Treasury securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in marketable debt securities. Our available-for-sale securities are subject to interest rate risk and will fall in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio. We have the ability to hold our available-sale-securities until maturity and therefore, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investments.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures. Based on that evaluation of our disclosure controls and procedures as of September 30, 2020, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of such date are effective at the reasonable assurance level. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act are recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may become involved in legal proceedings relating to claims arising from the ordinary course of business. Our management believes that there are currently no claims or actions pending against us, the ultimate disposition of which could have a material adverse effect on our results of operations, financial condition or cash flows.

Item 1A. Risk Factors

Investing in shares of our common stock involves a high degree of risk. You should carefully consider the following risks and uncertainties, together with all of the other information contained in this Quarterly Report on Form 10-Q, including "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes, before making an investment decision. The risks described below are not the only ones facing us. Many of the following risks and uncertainties are, and will be, exacerbated by the COVID-19 pandemic and any worsening of the global business and economic environment as a result. The occurrence of any of the following risks, or of additional risks and uncertainties not presently known to us or that we currently believe to be immaterial, could materially and adversely affect our business, financial condition, reputation, or results of operations. In such case, the trading price of shares of our common stock could decline, and you may lose all or part of your investment. We caution you that the risks, uncertainties and other factors referred to below and elsewhere in this Quarterly Report on Form 10-Q may not contain all of the risks, uncertainties and other factors that may affect our future results and operations. Moreover, new risks will emerge from time to time. It is not possible for our management to predict all risks. Below is a summary of some of the key risks that we face.

Summary of Key Risk Factors

- We have a limited operating history and have incurred significant losses since our inception, we expect to incur losses for the foreseeable future, and we may never achieve profitability.
- All of our product candidates are in preclinical or early-stage clinical development and clinical drug development is a lengthy and expensive process with uncertain timelines and outcomes.
- Results of preclinical studies of our product candidates may not be predictive of the results of future preclinical studies or clinical trials.
- Our product candidates may have serious adverse, undesirable, or unacceptable side effects or other properties that may delay or prevent marketing approval.
- Public health crises such as pandemics or similar outbreaks could materially and adversely affect our preclinical studies and clinical trials, business, financial condition, and results of operations. For example, we have experienced delays in our clinical trial of SL-279252 as a result of the ongoing COVID-19 pandemic, including delays with certain third-party vendors supporting this trial. As "shelter in place" orders and other public health guidance measures are reinstated in the locations of our clinical trial sites, we expect that some patients may also choose to forego one or more doses in our clinical trials due to challenges faced by such patients in travelling to our clinical trial sites, which may negatively affect the study results.
- We depend on the enrollment of patients in our clinical trials for our product candidates and if we experience delays or difficulties in the enrollment of patients in clinical trials, including as a result of competition for patients or the ongoing COVID-19 pandemic, we may be unable to complete these trials on a timely basis, if at all.
- The development and commercialization of biopharmaceutical products is subject to extensive regulation.

- We operate in highly competitive and rapidly changing industries, which may result in others discovering, developing, or commercializing competing products before or more successfully than we do.
- We rely on patents and other intellectual property rights to protect our technology, including product candidates and our ARC and GADLEN product candidates and other product candidates, the prosecution, enforcement, defense, and maintenance of which may be challenging and costly.
- We may need to obtain additional licenses of third-party technology that may not be available to us or are available only on commercially unreasonable terms, and which may cause us to operate our business in a more costly or otherwise adverse manner that was not anticipated.
- We will require substantial funding for our business, which may not be available to us on acceptable terms, or at all.

Risks Related to Our Business

We are an early clinical-stage biotechnology company and have incurred significant losses since our inception, and we expect to incur losses for the foreseeable future. We have no products approved for commercial sale and may never achieve or maintain profitability.

We are a clinical-stage biotechnology company with a limited operating history. Biotechnology product development is a highly speculative undertaking and involves a substantial degree of risk. We have incurred significant operating losses since inception. For the years ended December 31, 2018 and 2019 and for the nine months ended September 30, 2020, we reported a net loss of $7.4 million, $24.0 million, and $24.6 million, respectively. As of September 30, 2020, we have an accumulated deficit of $60.1 million. Our losses have resulted principally from expenses incurred in the research and development of our product candidates and from management and administrative costs and other expenses that we have incurred while building our business infrastructure. We expect to continue to incur significant operating losses for the foreseeable future as we continue our research and development efforts and seek to obtain regulatory approval and commercialization of our product candidates. We anticipate that our expenses will increase substantially as we:

- continue to advance the preclinical and clinical development of our lead product candidates;
- initiate preclinical studies and clinical trials for additional product candidates that we may identify in the future;
- expand our operational, financial, and management systems and increase personnel, including personnel to support our clinical development, manufacturing, and commercialization efforts;
- continue to develop, perfect, and defend our intellectual property portfolio; and
- incur additional legal, accounting, or other expenses in operating our business, including the additional costs associated with operating as a public company.

We have financed our operations to date primarily through the proceeds of our initial public offering, private financings and payments received under a collaboration agreement. We have devoted a significant portion of our financial resources and efforts to developing our ARC platform, identifying potential product candidates, conducting preclinical studies of a variety of product candidates, and preparing for and conducting clinical trials of product candidates. We are in the early stages of development of our product candidates, and we have not completed development and commercialization of any product candidate.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, discovering and developing additional product candidates, obtaining regulatory approval for any product candidates that successfully complete clinical trials, accessing manufacturing capacity, establishing marketing capabilities, and ultimately selling any products for which we may obtain regulatory approval. We may never succeed in any or all of these activities and, even if we do, we may never generate revenue that is sufficient to achieve profitability.

Because of the numerous risks and uncertainties associated with pharmaceutical products and biological development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will

be able to achieve profitability. If we are required by the U.S. Food and Drug Administration, or FDA, or other regulatory authorities to perform studies in addition to those we currently anticipate, or if there are any delays in completing our clinical trials or the development of any of our product candidates, our expenses could increase and commercial revenue could be further delayed and more uncertain.

Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

Since our inception in 2016, we have devoted a significant portion of our resources to developing our product candidates, our other research and development efforts, building our intellectual property portfolio, raising capital, and providing general and administrative support for these operations. While we are evaluating SL-172154 in two ongoing Phase 1 clinical trials and are also evaluating SL-279252 in a Phase 1 clinical trial, we have not completed a clinical trial for any product candidate. We have not yet demonstrated our ability to successfully complete clinical trials (including Phase 3 or other pivotal clinical trials), obtain regulatory approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Additionally, we expect our financial condition and operating results to continue to fluctuate significantly from period to period due to a variety of factors, many of which are beyond our control. Consequently, any predictions you may make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

We will require additional funding in order to complete development of our product candidates and commercialize our products, if approved. This additional financing may not be available on acceptable terms, or at all. If we are unable to raise capital when needed, we could be forced to delay, reduce, or eliminate our product development programs or commercialization efforts.

To date, we have funded our operations primarily through the proceeds of our initial public offering, private financings and payments received under a collaboration agreement. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct our ongoing clinical trials of SL-172154 and SL-279252, initiate additional clinical trials, and continue to research, develop, and conduct preclinical studies of our other product candidates.

In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales, and distribution. Furthermore, we have and will continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce, or eliminate our research and development programs or any future commercialization efforts.

Based on our current business plans, we believe that our existing cash and cash equivalents and short-term investments, will enable us to fund our operating expenses through the end of 2024. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect, requiring us to seek additional funds sooner than planned, through public or private equity or debt financings or other sources, such as strategic collaborations. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop our product candidates. Our future capital requirements will depend on many factors, including:

- the scope, timing, progress, costs, and results of discovery, preclinical development, laboratory testing, and clinical trials for our product candidates;
- the costs, timing, and outcome of regulatory review of any of our product candidates;
- the cost of manufacturing clinical supplies of our product candidates;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales, and distribution, for any of our product candidates for which we receive marketing approval;

- 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 progress of our collaboration with Takeda to develop product candidates;
- the costs and timing of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property rights, and defending any intellectual property-related claims, including any claims by third parties that we are infringing upon their intellectual property rights;
- 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;
- the cost of building a sales force in anticipation of product commercialization;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in business, products, and technologies

Our ability to raise additional funds will depend on financial, economic, and market conditions and other factors, over which we may have no or limited control. Market volatility resulting from the COVID-19 pandemic or other factors could also adversely impact our ability to access capital as and when needed. 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 could 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;
- delay, limit, reduce, or terminate our efforts to access manufacturing capacity, establish sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates, or reduce our flexibility in developing or maintaining our sales and marketing strategy.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations, or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our operations with our existing cash and cash equivalents and short-term investments, the net proceeds from our initial public offering, equity or debt financings, and upfront and milestone and royalties payments, if any, received under our collaboration with Takeda and any other future licenses or collaborations. If we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our existing stockholders' rights as holders of our common stock. In addition, the possibility of such issuance may cause the market price of our common stock to decline. Debt financing, if available, may result in increased fixed payment obligations and involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends, or acquiring, selling, or licensing intellectual property rights, which could adversely impact our ability to conduct our business.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution, or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, technologies, future revenue streams, or product candidates or grant licenses on terms that may not be favorable to us. We could also be required to seek funds through arrangements with collaborators or others at an earlier stage than otherwise would be desirable. Any of these occurrences may have a material adverse effect on our business, operating results, and prospects.

Public health crises such as pandemics or similar outbreaks could materially and adversely affect our preclinical and clinical trials, business, financial condition, and results of operations.

In March 2020, the World Health Organization declared COVID-19 a global pandemic and the United States declared a national emergency with respect to COVID-19. In response to the COVID-19 pandemic, "shelter in place" orders and other public health guidance measures have been implemented across much of the United States, including in the locations of our offices, clinical trial sites, key vendors, and partners. We have experienced delays in our clinical trials of SL-279252 and SL-172154 as a result of the ongoing pandemic, including delays with certain third-party vendors supporting these trials. We temporarily paused enrollment of patients for our clinical trial of SL-279252 between March and May 2020, and we resumed enrollment in June 2020. As "shelter in place" orders and other public health guidance measures are reinstated in the locations of our clinical trial sites, we expect that some patients may also choose to forego one or more doses in our clinical trials, due to challenges faced by such patients in travelling to our clinical trial sites, which may negatively affect the study results. We expect that our clinical development program timelines may continue to be negatively affected by COVID-19, which could materially and adversely affect our business, financial condition, and results of operations. Further, due to "shelter in place" orders and other public health guidance measures, we may be required to implement a work-from-home policy for all staff members excluding those necessary to maintain minimum basic operations. In such an instance, our increased reliance on personnel working from home may negatively impact productivity, or disrupt, delay, or otherwise adversely impact our business. For example, with our personnel working from home, some of our research activities that require our personnel to be in our laboratories may be delayed.

As a result of the COVID-19 pandemic, or similar pandemics, and related "shelter in place" orders and other public health guidance measures, we have and may in the future experience disruptions that could materially and adversely impact our clinical trials, business, financial condition, and results of operations. Potential disruptions include but are not limited to:

- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in initiating or expanding clinical trials, including delays or difficulties with clinical site initiation and recruiting clinical site investigators and clinical site staff;
- increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting COVID-19 or other health conditions or being forced to quarantine;
- interruption of key clinical trial activities, such as clinical trial site data monitoring and efficacy, safety and translational data collection, processing and analyses, due to limitations on travel imposed or recommended by federal, state, or local governments, employers and others or interruption of clinical trial subject visits, which may impact the collection and integrity of subject data and clinical study endpoints;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- delays or disruptions in preclinical experiments and IND-enabling studies due to restrictions of on-site staff and unforeseen circumstances at contract research organizations, or CROs, and vendors;
- interruption or delays in the operations of the FDA and comparable foreign regulatory agencies;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns, or stoppages and disruptions in delivery systems;
- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- limitations on employee or other resources that would otherwise be focused on the conduct of our clinical trials and pre-clinical work, including because of sickness of employees or their families, the desire of employees to avoid travel or contact with large groups of people, an increased reliance on working from home, school closures, or mass transit disruptions;
- changes in regulations as part of a response to the COVID-19 pandemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;

- delays in necessary interactions with regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government or contractor personnel; and
- refusal of the FDA to accept data from clinical trials in affected geographies outside the United States.

The COVID-19 global pandemic continues to rapidly evolve. The extent to which the outbreak may affect our clinical trials, business, financial condition, and results of operations will depend on future developments, which are highly uncertain and cannot be predicted at this time, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions, and actions to contain the outbreak or treat its impact, such as social distancing and quarantines or lock-downs in the United States and other countries, business closures, or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. Future developments in these and other areas present material uncertainty and risk with respect to our clinical trials, business, financial condition, and results of operations.

If we or our collaborators are unable to successfully develop and commercialize our product candidates, or experience significant delays in doing so, our business, financial condition, and results of operations will be materially adversely affected.

Our ability to generate product and royalty revenues, which we do not expect will occur for at least the next several years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates, which may never occur. We currently generate no revenue from sales of any products, and we may never be able to develop or commercialize a marketable product. Each of our product candidates and any future product candidates we develop will require significant clinical development; management of clinical, preclinical, and manufacturing activities; regulatory approval in multiple jurisdictions; establishing manufacturing supply, including commercial manufacturing supply; and require us to build a commercial organization and make substantial investment and significant marketing efforts before we generate any revenue from product sales. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates.

The successful development of our product candidates will depend on several factors, including the following:

- successful and timely completion of clinical trials and preclinical studies for which the FDA, or any comparable foreign regulatory authority agree with the design, endpoints, or implementation;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- receiving regulatory approvals or authorizations for conducting our planned clinical trials or future clinical trials;
- initiation and successful patient enrollment in, and completion of, additional clinical trials on a timely basis;
- our ability to demonstrate to the satisfaction of the FDA or any comparable foreign regulatory authority that the applicable product candidate is safe and effective as a treatment for our targeted indications or, in the case of an applicable product candidates which is regulated as a biological product, that the applicable product is safe, pure, and potent for our targeted indications;
- our ability to demonstrate to the satisfaction of the FDA or any comparable foreign regulatory authority that the applicable product candidate's risk-benefit ratio for its proposed indication is acceptable;
- timely receipt of marketing approvals for our product candidates from applicable regulatory authorities;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities; and
- establishing and scaling up, either alone or with third-party manufacturers, manufacturing capabilities of clinical supply for our clinical trials and commercial manufacturing, if any of our product candidates are approved.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully develop and commercialize our product candidates, which would materially adversely affect our business, financial condition, and results of operations.

Our ARC platform is based on novel technologies that are unproven and may not result in approvable or 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, and we may not be successful in our efforts to use and expand our technology platforms, including ARC and GADLEN, to build a pipeline of product candidates.

We are developing a pipeline of product candidates using our proprietary ARC platform. We have not received regulatory approval for any of our ARC product candidates. The scientific research that forms the basis of our efforts to develop product candidates with our ARC platform is still ongoing. Further, the scientific evidence to support the feasibility of developing therapeutic treatments based on our ARC platform is both preliminary and limited. Given the novelty of our technologies, we intend to work closely with the FDA and other regulatory authorities to perform the requisite scientific analyses and evaluation of our methods to obtain regulatory approval for our product candidates. The validation process takes time and resources, may require independent third-party analyses, and may not be accepted by the FDA and other regulatory authorities. We cannot be certain that our approach will lead to the development of approvable or marketable products, alone or in combination with other therapies. Our approach combines two binding domains to create fusion proteins that potentially restore and enhance immune system function in a single construct, which is unproven and may not be successful. To our knowledge, our dual-sided fusion protein product candidates have not been tested before in humans and may have properties that negatively impact safety and efficacy, such as greater immunogenicity when compared to existing antibody therapeutics. Moreover, the dual-sided nature of our product candidates may have unexpected biological interactions when administered *in vivo*. For example, it may be necessary to either implement a loading dose strategy or delay enrollment of patients recently treated with anti-PD-1 antibodies to mitigate interactions between anti-PD-1 antibodies and SL-279252. Finally, the FDA or other regulatory agencies may lack experience in evaluating the safety and efficacy of our ARC platform, which could result in a longer than expected regulatory review process, increase our expected development costs, and delay or prevent commercialization of our product candidates.

Additionally, a key element of our strategy is to use and expand our technology platforms, including ARC and GADLEN, to build a pipeline of product candidates and progress these product candidates through clinical development for the treatment of a variety of different types of diseases. Although our research and development efforts to date have resulted in a pipeline of product candidates directed at various cancers and autoimmune diseases, we may not be able to develop product candidates that are safe and effective. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. If we do not continue to successfully develop and begin to commercialize product candidates, we will face difficulty in obtaining product revenues in future periods, which could result in significant harm to our financial position and adversely affect our share price.

We expect to continue to expand our development and regulatory capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of November 1, 2020, we had 57 full-time employees. We expect to experience continued growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs and, ultimately, sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational, and financial systems; expand our facilities; and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

In addition, future growth imposes significant added responsibilities on members of management, including: identifying, recruiting, integrating, maintaining, and motivating additional employees; managing our internal

development efforts effectively, including the clinical and FDA review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and improving our operational, financial and management controls, reporting systems, and procedures.

We currently rely on certain independent organizations, advisors, and consultants to provide certain services, including strategic, financial, business development services, as well as certain aspects of regulatory approval, clinical management, manufacturing, and preparation for a potential commercial launch. There can be no assurance that the services of independent organizations, advisors, and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants or contract manufacturing organizations is compromised for any reason, our clinical trials may be extended, delayed, or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

Our future growth and ability to compete depends on retaining our key personnel and recruiting additional qualified personnel.

Our success depends upon the continued contributions of our key management, scientific, and technical personnel, many of whom have been instrumental for us and have substantial experience with our product candidates and related technologies. The loss of key managers and senior scientists could delay our research and development activities. Despite our efforts to retain valuable employees, members of our management, scientific, and development teams may terminate their employment with us on short notice. Although we have employment agreements with certain of our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. In addition, the competition for qualified personnel in the biotechnology and pharmaceutical industries is intense, and our future success depends upon our ability to attract, retain, and motivate highly-skilled scientific, technical, and managerial employees. We face competition for personnel from other companies, universities, public and private research institutions, and other organizations. If our recruitment and retention efforts are unsuccessful in the future, it may be difficult for us to implement our business strategy, which could have a material adverse effect on our business.

Risks Related to the Development and Clinical Testing of Our Product Candidates

Our clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of our product candidates or any future product candidates, which would prevent or delay or limit the scope of regulatory approval and commercialization.

To obtain the requisite regulatory approvals to market and sell any of our product candidates and any other future product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our investigational drug products are safe and effective for use in each targeted indication. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical development process. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful, and a clinical trial can fail at any stage of testing.

Further, the process of obtaining regulatory approval is expensive, often taking many years following the commencement of clinical trials, and can vary substantially based upon the type, complexity, and novelty of the product candidates involved, as well as the target indications, patient population, and regulatory agency. Prior to obtaining approval to commercialize our product candidates and any future product candidates in the United States or abroad, we, our collaborators or our potential future collaborators must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses.

Clinical trials that we conduct may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols, and the rate of dropout among clinical trial participants. If the results

of our ongoing or future clinical trials are inconclusive with respect to the efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may be delayed in obtaining marketing approval, if at all. Additionally, any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications.

Even if the trials are successfully completed, clinical data are often susceptible to varying interpretations and analyses, and we cannot guarantee that the FDA or comparable foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. We cannot guarantee that the FDA or comparable foreign regulatory authorities will view our product candidates as having efficacy even if positive results are observed in clinical trials. Moreover, results acceptable to support approval in one jurisdiction may be deemed inadequate by another regulatory authority to support regulatory approval in that other jurisdiction. To the extent that the results of the trials are not satisfactory to the FDA or comparable foreign regulatory authorities for support of a marketing application, approval of our product candidates and any future product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Even if regulatory approval is secured for a product candidate, the terms of such approval may limit the scope and use of the specific product candidate, which may also limit its commercial potential.

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

From time to time, we may publicly disclose preliminary or topline data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions, or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product, and our company in general. If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects, or financial condition.

Results of preclinical studies of our product candidates may not be predictive of the results of future preclinical studies or clinical trials.

To obtain the requisite regulatory approvals to market and sell any of our product candidates, we or any collaborator for such candidates must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe, pure, and potent in humans. Before an IND can be submitted to the FDA and become effective, which is a prerequisite for conducting clinical trials on human subjects, a product candidate must successfully progress through extensive preclinical studies, which include preclinical laboratory testing, animal studies, and formulation studies in accordance with Good Laboratory Practices.

Success in preclinical studies does not ensure that later preclinical studies or 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. 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. The design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses. Notwithstanding any potential promising results in earlier studies, we cannot be certain that we will not face similar setbacks. 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 subsequent clinical trials on human subjects. Product candidates in clinical trials may fail to show the desired pharmacological properties or safety and efficacy traits despite having progressed through preclinical studies.

If we fail to receive positive results in preclinical studies or clinical trials of our product candidates, the development timeline and regulatory approval and commercialization prospects for our most advanced product candidates, and, correspondingly, our business and financial prospects would be negatively impacted.

All of our product candidates are in preclinical or early-stage clinical development. Clinical drug development is a lengthy and expensive process with uncertain timelines and uncertain outcomes. If clinical trials of our product candidates are prolonged or delayed, we or any collaborators may be unable to obtain required regulatory approvals, and therefore be unable to commercialize our product candidates on a timely basis or at all.

Clinical testing 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. Product candidates in later stages of clinical trials may fail to produce the same results or to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Our future clinical trial results may not be successful.

Additionally, some of our trials, including our ongoing Phase 1 trial evaluating SL-279252 and Phase 1 trial evaluating SL-172154, are open-label trials in which both the patient and investigator know whether the patient is receiving the investigational product candidate or an existing approved therapy. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect, as patients in open-label clinical trials are aware when they are receiving treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. Therefore, it is possible that positive results observed in open-label trials will not be replicated in later placebo-controlled trials.

To date, we have not completed any clinical trials required for the approval of our product candidates. We may experience delays in our ongoing clinical trials, and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time, or be completed on schedule, if at all. Clinical trials can be delayed, suspended, or terminated for a variety of reasons, including the following:

- delays in or failure to obtain regulatory authorization to commence a trial;
- delays in or failure to obtain institutional review board, or IRB, approval at each site;
- delays in or failure to reach 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;
- difficulty in recruiting clinical trial investigators of appropriate competencies and experience;
- delays in establishing the appropriate dosage levels in clinical trials;
- delays in or failure to recruit and enroll suitable patients to participate in a trial, particularly considering study inclusion and exclusion criteria and patients’ prior lines of therapy and treatment;
- the difficulty in certain countries in identifying the sub-populations that we are trying to treat in a particular trial, which may delay enrollment and reduce the power of a clinical trial to detect statistically significant results;

- lower than anticipated retention rates of patients in clinical trials;
- failure to have patients complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a trial;
- delays adding new investigators or clinical trial sites;
- safety or tolerability concerns could cause us or our collaborators or governmental authorities, as applicable, to suspend or terminate a trial if it is found that the participants are being exposed to unacceptable health risks, undesirable side effects, or other unfavorable characteristics of the product candidate, or if such undesirable effects or risks are found to be caused by a chemically or mechanistically similar therapeutic or therapeutic candidate;
- our third-party research contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- changes in regulatory requirements, policies, and guidelines;
- manufacturing sufficient quantities of a product candidate for use in clinical trials;
- the quality or stability of a product candidate falling below acceptable standards;
- changes in the treatment landscape for our target indications that may make our product candidates no longer relevant;
- third-party actions claiming infringement by our product candidates in clinical trials outside the United States and obtaining injunctions interfering with our progress; and
- business interruptions resulting from geo-political actions, including war and terrorism, natural disasters including earthquakes, typhoons, floods, and fires, or disease, including the COVID-19 pandemic.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting, or completing our planned and ongoing clinical trials. Moreover, while we plan to submit additional INDs for other drug candidates, we may not be able to file such INDs on the timeline we expect. For example, we may experience manufacturing delays or other delays with IND-enabling preclinical studies. Moreover, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate clinical trials. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND, we cannot guarantee that such regulatory authorities will not change their requirements in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs.

Clinical trials must be conducted in accordance with the FDA and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and Ethics Committees or IRBs at the medical institutions where the clinical trials are conducted. We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs or Ethics Committees of the institutions in which such trials are being conducted, by the Data Review Committee or Data Safety Monitoring Board for such trial or by the FDA, or other regulatory authorities. Such authorities may impose such a suspension or termination 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 drug, changes in governmental regulations or administrative actions, or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process, and jeopardize our ability to commence product sales and generate revenues. Significant clinical trial delays could also allow our competitors to bring products to market before we do or shorten any periods during which we have the exclusive right to commercialize our product candidates and impair our ability to commercialize our product candidates and may harm our business and results of operations.

In addition, clinical trials must be conducted with supplies of our product candidates produced under current good manufacturing practices, or cGMP, requirements and other regulations. Furthermore, we rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance. We depend on our collaborators and on medical institutions and CROs to conduct our clinical trials in compliance with good clinical practice, or GCP, requirements. To the extent our collaborators or the CROs fail to enroll participants for our clinical trials, fail to conduct the study in accordance with GCP, or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays, or both, which may harm our business. In addition, clinical trials that are conducted in countries outside the United States may subject us to further delays and expenses as a result of increased shipment costs, additional regulatory requirements, and the engagement of non-U.S. CROs, as well as expose us to risks associated with clinical investigators who are unknown to the FDA, and different standards of diagnosis, screening, and medical care.

Our product candidates may have serious adverse, undesirable, or unacceptable side effects or other properties that may delay or prevent marketing approval. If such side effects are identified following approval, if any, the commercial profile of any approved label may be limited, or we may be subject to other significant negative consequences following marketing approval, if any.

Undesirable side effects that may be 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 other comparable foreign authorities. While we believe that the targeted nature of our dual-sided fusion proteins may carry a lower risk of overstimulating the immune system and causing a cytokine storm (a side effect associated with certain other antibody therapies), we do not have enough clinical data and experience with these molecules in humans to fully anticipate side effects. Accordingly, we may experience unexpected side effects and/or higher levels of known side effects in clinical trials, such as cytokine storms associated with immune checkpoint inhibitors or red blood cell lysis associated with SIRPα therapies.

Results of our clinical trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our clinical trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the clinical trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition, and prospects significantly.

Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate.

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

- regulatory authorities may withdraw or limit approvals of such products and require us to take our approved product off the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies, or issue other communications containing warnings or other safety information about the product;
- regulatory authorities may require a medication guide outlining the risks of such side effects for distribution to patients, or that we implement a risk evaluation and mitigation strategy, or REMS, plan to ensure that the benefits of the product outweigh its risks;
- we may be required to change the dose or the way the product is administered, conduct additional clinical trials, or change the labeling of the product;
- we may be subject to limitations on how we may promote or manufacture the product;
- sales of the product may decrease significantly;

- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us, our collaborators, or our potential future partners from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of any products.

The manufacture of our product candidates is complex. Our third-party manufacturers may encounter difficulties in production, which could delay or entirely halt their ability to supply our product candidates for clinical trials or, if approved, for commercial sale.

Our product candidates are considered to be biologics, and the process of manufacturing biologics is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. We do not own or operate any cGMP manufacturing facilities. We rely, and expect to continue to rely, on third-party contract development and manufacturing organizations for the manufacture of our product candidates for preclinical and clinical testing. To date, we and our contract manufacturers have limited experience in the manufacturing of cGMP batches of our product candidates. Our contract manufacturers must comply with cGMPs, regulations, and guidelines for the manufacturing of biologics used in clinical trials and, if approved, marketed products. To date, we and our contract manufacturers have only produced smaller cGMP batches of our product candidates and have not scaled up the manufacturing process for later-stage clinical trials and commercialization. Larger scale manufacturing will require the development of new processes, including for the removal of impurities that are a normal byproduct of the manufacturing process. The nature of our dual-sided fusion proteins requires the development of novel manufacturing and purification processes, which could cause delays in the scale-up of manufacturing, as well as greater costs that could negatively impact the financial viability of our product candidates. Moreover, the nature of our dual-sided fusion proteins creates challenges for the stability of the drug substance, which has the potential to cause delays in completing clinical studies and potentially limiting clinical trial site locations based on applicable regulations.

The process of manufacturing our biologic product candidates is extremely susceptible to product loss due to contamination, oxidation, equipment failure, or improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics, and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, and other supply disruptions. If microbial, viral, or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, this could lead to withdrawal of our products from the market, and such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Moreover, if the FDA determines that our third-party manufacturers are not in compliance with FDA laws and regulations, including those governing cGMPs, the FDA may deny BLA approval until the deficiencies are corrected or we replace the manufacturer in our BLA with a manufacturer that is in compliance.

Any adverse developments affecting manufacturing operations for our product candidates, if any are approved, may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our products. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications as a result of defects or storage over an extended period of time, undertake costly remediation efforts, or seek more costly manufacturing alternatives. As part of our process development efforts, 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.

We depend on enrollment of patients in our clinical trials for our product candidates. If we experience delays or difficulties enrolling in our clinical trials, our research and development efforts and business, financial condition, and results of operations could be materially adversely affected.

Successful and timely completion of clinical trials will require that we enroll a sufficient number of patient candidates. These trials and other trials we conduct may be subject to delays for a variety of reasons, including as a result of patient enrollment taking longer than anticipated, patient withdrawal, or adverse events. For example, we have experienced delays in our clinical trials of SL-279252 and SL-172154 as a result of the ongoing pandemic. These types of developments could cause us to delay the trials or halt further development.

Our clinical trials will compete with other clinical trials that are in the same therapeutic areas as our product candidates, and this competition reduces the number and types of patients available to us, as 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. Moreover, enrolling patients in clinical trials for cancer therapies is challenging, as cancer patients will first receive the applicable standard of care. Many patients who respond positively to the standard of care antibody therapy, such as PD-1 checkpoint inhibitors, (and thus do not enroll in clinical trials) are believed to have tumor types that may have responded well to our product candidates. This may limit the number of eligible patients able to enroll in our clinical trials who have the potential to benefit from our drug candidates and could extend development timelines or increase costs for these programs. Patients who fail to respond positively to the standard of care treatment will be eligible for clinical trials of unapproved drug candidates. However, these patients may have either compromised immune function from prior administration of chemotherapy or an enhanced immune response from the prior administration of checkpoint inhibitors. Either of these prior treatment regimens may render our therapies less effective in clinical trials. We may seek to mitigate these effects in the future through modification of enrollment eligibility criteria, including patients with tumor types that are not typically responsive to anti-PD-1 antibodies, or pursuing combination regimens early in clinical development to enable access to anti-PD-1 naive patients. Additionally, patients who have failed approved therapies will typically have more advanced cancer and a poorer long-term prognosis.

Because the number of qualified clinical investigators and clinical trial sites is limited, we expect to 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 at such clinical trial sites.

Patient enrollment depends on many factors, including:

- the size and nature of the patient population;
- the severity of the disease under investigation;
- eligibility criteria for the trial;
- the proximity of patients to clinical sites;
- the design of the clinical protocol;
- the ability to obtain and maintain patient consents;
- the ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the risk that patients enrolled in clinical trials will drop out of the trials before the administration of our product candidates or trial completion;
- the availability of competing clinical trials;
- the availability of new drugs approved for the indication the clinical trial is investigating; and
- clinicians’ and patients’ perceptions as to the potential advantages of the drug being studied in relation to other available therapies.

These factors may make it difficult for us to enroll enough patients to complete our clinical trials in a timely and cost-effective manner. Delays in the completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development and approval process, and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, some 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.

We may become exposed to costly and damaging liability claims, either when testing our product candidates in the clinic or at the commercial stage, and our product liability insurance may not cover all damages from such claims.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing, and use of pharmaceutical products. While we currently have no products that have been approved for commercial sale, the current and future use of product candidates by us and our partners in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients that use the product, healthcare providers, pharmaceutical companies, our partners, or others selling such products. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially adversely affect the market for our product candidates or any prospects for commercialization of our product candidates.

Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If any of our product candidates were to cause adverse side effects during clinical trials or after approval of the product candidate, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates.

Even successful defense against product liability claims would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: decreased demand for our product candidates; injury to our reputation; withdrawal of clinical trial participants; initiation of investigations by regulators; costs to defend the related litigation; a diversion of management's time and our resources; substantial monetary awards to trial participants or patients; product recalls, withdrawals or labeling, marketing or promotional restrictions; loss of revenue; exhaustion of any available insurance and our capital resources; the inability to commercialize any product candidate; and a decline in our share price.

Although we maintain adequate product liability insurance for our product candidates, it is possible that our liabilities could exceed our insurance coverage. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for any of our product candidates. However, we may be unable to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims, and our business operations could be impaired.

Risks Related to Our Regulatory Environment

The development and commercialization of biopharmaceutical products is subject to extensive regulation, and the regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming, and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates on a timely basis if at all, our business will be substantially harmed.

The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, import, marketing, distribution, adverse event reporting, including the submission of safety and other post-marketing information and reports, and other possible activities relating to our product candidates are subject to extensive regulation. In the United States, marketing approval of biologics requires the submission of a Biologics License Application, or BLA, to the FDA, and we are not permitted to market any product candidate in the United States until we obtain approval from the FDA of the BLA for that product candidate. A BLA must be supported by extensive clinical and preclinical data, as well as extensive information regarding pharmacology, chemistry, manufacturing, and controls. Outside the United States, many comparable foreign regulatory authorities employ similar approval processes.

We have not previously submitted a BLA to the FDA or similar regulatory approval filings to comparable foreign authorities, for any product candidate, and we cannot be certain that any of our product candidates will receive regulatory approval. We are not permitted to market our product candidates in the United States or in other countries until we receive approval of a BLA from the FDA or marketing approval from applicable regulatory authorities outside the United States. Obtaining approval of a BLA can be a lengthy, expensive, and uncertain process, and as a company we have no experience with the preparation of a BLA submission or any other

application for marketing approval. In addition, the FDA has the authority to require a risk evaluation and mitigation strategies, or REMS, plan as part of a BLA or after approval, which may impose further requirements or restrictions on the distribution or use of an approved biologic, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA or other submission or to obtain regulatory approval in the United States or elsewhere, or regulatory authorities may not accept a submission due to, among other reasons, the content or formatting of the submission;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations, and prospects. The FDA and other regulatory authorities have substantial discretion in the approval process, and determining when or whether regulatory approval will be obtained for any of our product candidates. For example, regulatory authorities in various jurisdictions have in the past had, and may in the future have, differing requirements for, interpretations of and opinions on our preclinical and clinical data. As a result, we may be required to conduct additional preclinical studies, alter our proposed clinical trial designs, or conduct additional clinical trials to satisfy the regulatory authorities in each of the jurisdictions in which we hope to conduct clinical trials and develop and market our products, if approved. Further, even if we believe the data collected from clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA or any other regulatory authority.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Even if our product candidates obtain regulatory approval, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

If the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, import, export, adverse event reporting, storage, advertising, promotion, and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval, all of which may result in significant expense and limit our ability to commercialize such products. In addition, any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate.

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.

If there are changes in the application of legislation or regulatory policies, or if problems are discovered with a product or our manufacture of a product, or if we or one of our distributors, licensees or co-marketers fails to comply with regulatory requirements, the regulators could take various actions. These include issuing warning letters or untitled letters, imposing fines on us, imposing restrictions on the product or its manufacture, and requiring us to recall or remove the product from the market. The regulators could also suspend or withdraw our marketing authorizations, requiring us to conduct additional clinical trials, change our product labeling, or submit additional applications for marketing authorization. If any of these events occurs, our ability to sell such product may be impaired, and we may incur substantial additional expense to comply with regulatory requirements, which could materially adversely affect our business, financial condition, and results of operations.

In addition, if we have any product candidate approved, our product labeling, advertising, and promotion will be subject to regulatory requirements and continuing regulatory review. In the United States, the FDA and the Federal Trade Commission, or FTC, strictly regulate the promotional claims that may be made about pharmaceutical products to ensure that any claims about such products are consistent with regulatory approvals, not misleading or false in any particular, and adequately substantiated by clinical data. The promotion of a drug product in a manner that is false, misleading, unsubstantiated, or for unapproved (or off-label) uses may result in enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA or the FTC. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions and may result in false claims litigation under federal and state statutes, which can lead to consent decrees, civil monetary penalties, restitution, criminal fines and imprisonment, and exclusion from participation in Medicare, Medicaid, and other federal and state healthcare programs. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

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;
- issue, or require us to issue, safety-related communications, such as safety alerts, field alerts, "Dear Doctor" letters to healthcare professionals, or import alerts;

- impose civil or criminal penalties;
- suspend, limit, or withdraw regulatory approval;
- suspend any of our preclinical studies and clinical trials;
- 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, refuse to permit the import or export of products, or require us to conduct 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 approved. 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, the 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 the 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.

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

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new biologics or modifications to licensed biologics 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 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown

occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Our research and development activities could be affected or delayed as a result of possible restrictions on animal testing.

Certain laws and regulations require us to test our product candidates on animals before initiating clinical trials involving humans. Animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting these activities through protests and other means. To the extent the activities of these groups are successful, our research and development activities may be interrupted, delayed, or become more expensive.

Our business operations and current and future relationships with healthcare professionals, principal investigators, consultants, vendors, customers, and third-party payors in the United States and elsewhere are subject to applicable anti-kickback, fraud and abuse, false claims, physician payment transparency, and other healthcare laws and regulations, which could expose us to substantial penalties, contractual damages, reputation harm, administrative burdens, and diminished profits.

Healthcare providers, healthcare facilities and institutions, physicians, and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, healthcare facilities and institutions, principal investigators, consultants, customers, and third-party payors may expose us to broadly applicable fraud and abuse and other healthcare laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, that may constrain the business or financial arrangements and relationships through which we research, sell, market, and distribute any product candidates for which we obtain marketing approval. In addition, we may be subject to physician payment transparency laws and regulation by the federal government and by the states and foreign jurisdictions in which we conduct our business. The applicable federal, state, and foreign healthcare laws that affect our ability to operate include, but are not limited to, the following:

- the 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. The term “remuneration” has been broadly interpreted to include anything of value, including stock options. The federal Anti-Kickback Statute has also been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other the other hand. Any arrangements with prescribers must be for *bona fide* services and compensated at fair market value. 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. In addition, on July 24, 2020, President Trump issued an Executive Order directing the Department of Health and Human Services, or HHS, to engage in rulemaking to eliminate the safe harbor protections under the Anti-Kickback Statute that cover rebates for health plan sponsors and pharmacy benefit managers, and instead protect the application of discounts at the patients’ point of sale, in an effort to ensure that discounts on prescription drugs are passed directly to patients;
- 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, among other things, 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 federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- the federal Health Insurance Portability and Accountability Act of 1996, or 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 federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation.
- the U.S. Federal Food, Drug, and Cosmetic Act, or 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, among other things, 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 Centers for Medicare and Medicaid Services, or CMS, information related to certain payments and other transfers of value to physicians, as defined by statute, and teaching hospitals, as well as ownership and investment interests held by such physicians and their immediate family members. Beginning in 2022, such obligations will include payments and other transfers of value provided in the previous year to certain other healthcare professionals, including physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives;
- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements, and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and state and local laws requiring the registration of pharmaceutical sales representatives; and
- similar healthcare laws and regulations in foreign 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 not always possible to identify and deter employee misconduct or business noncompliance, and the precautions we take to detect and prevent inappropriate conduct 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. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. We have entered into consulting and scientific advisory board arrangements with physicians and other healthcare providers, including some who could influence the use of our product candidates, if approved. Compensation under some of these arrangements includes the provision of stock or stock options in addition to cash consideration. Because of the complex and far-reaching nature of these laws, it is possible that governmental authorities could conclude that our payments to physicians may not be fair market value for *bona fide* services or 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 noncompliance, 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.

Our employees, independent contractors, principal investigators, consultants, commercial partners, and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other misconduct. We cannot ensure that our compliance controls, policies, and procedures will in every instance protect us from acts committed by our employees, agents, contractors, or collaborators that would violate the laws or regulations of the jurisdictions in which we operate, including, without limitation, employment, foreign corrupt practices, trade restrictions and sanctions, environmental, competition, and patient privacy and other privacy laws and regulations. Misconduct by employees could include failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we may establish, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately, or disclose unauthorized activities to us. In particular, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, labeling, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations.

If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material and adverse effect on our business, financial condition, results of operations and prospects, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, individual imprisonment, disgorgement of profits, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of noncompliance with the law, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and pursue our strategy.

Current and future legislation may increase the difficulty and cost for us and any future collaborators to obtain marketing approval of and commercialize our product candidates and affect the prices we, or they, may obtain.

In the United States 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 of importance to the pharmaceutical and biotechnology industries, which includes biologics, are the following:

- manufacturers and importers of certain branded prescription drugs, including certain biologics, with annual sales of more than $5 million made to or covered by specified federal healthcare programs are required to pay an annual, nondeductible fee according to their market share of all such sales;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, to 23.1% of the average manufacturer price for most branded drugs, biologics, and biosimilars and to 13.0% for generic drug, and cap of the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price, or AMP;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics, including our product candidates, that are inhaled, infused, instilled, implanted, or injected;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health program, commonly referred to as the "340B Program;"
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians, also known as the "Physicians Payment Sunshine Act;"
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- establishment of a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending; and
- a licensure framework for follow-on biologic products.

Since its enactment, there have been judicial and Congressional 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, repealed the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage that is commonly referred to as the "individual mandate." In December 2019, a U.S. District Court upheld a ruling that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. In March 2020, the Supreme Court of the United States agreed to hear the appeal of this decision. It is unclear how this and other efforts to challenge, repeal, or replace the ACA will impact the ACA or our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted which, among other things, have reduced Medicare payments to several types of providers, including hospitals and cancer treatment centers. These new laws or any other similar laws introduced in the future, as well as regulatory actions that may be taken by CMS, may result in additional reductions in Medicare and other healthcare 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. Additionally, individual states in the United States have passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing and costs. Similar developments have occurred outside of the United States, including in the European Union where healthcare budgetary constraints have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. To obtain reimbursement or pricing approval in some European Union member states, we may be required to conduct studies that compare the cost-effectiveness of our product candidates to other therapies that are considered the local standard of care.

We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action in the United States 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.

Even if we are able to commercialize any product candidate, coverage and adequate reimbursement may not be available or such product candidate may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business.

The regulations that govern regulatory approvals, pricing, and reimbursement for drug products vary widely from country to country. Some countries require approval of the sale price of a drug product before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, prescription drug product pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain regulatory approval.

Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payors, such as government authorities, private health insurers, and other organizations. Even if we succeed in bringing one or more products to the market, these products may not be considered cost-effective, and the amount reimbursed for any products may be insufficient to allow us to sell our products on a competitive basis. Because our programs are in the early stages of development, we are unable at this time to determine their cost effectiveness or the likely level or method of coverage and reimbursement. Increasingly, the third-party payors who reimburse patients or healthcare providers are requiring that drug companies provide them with predetermined discounts from list prices, and are seeking to reduce the prices charged or the amounts reimbursed for drug products. If the price we are able to charge for any products we develop, or the coverage and reimbursement provided for such products, is inadequate in light of our development and other costs, our return on investment could be affected adversely.

There may be significant delays in obtaining reimbursement for newly-approved drug products, and coverage may be more limited than the purposes for which the drug product is approved by the FDA or similar foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drugs product will be reimbursed in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution.

Interim reimbursement levels for new drug products, if applicable, may also be insufficient to cover our costs and may not be made permanent. Reimbursement rates may be based on payments allowed for lower cost drug products that are already reimbursed, may be incorporated into existing payments for other services and may reflect budgetary constraints or imperfections in Medicare data. Net prices for drug products may be reduced by mandatory discounts or rebates required by third-party payors and by any future relaxation of laws that presently restrict imports of drug products from countries where they may be sold at lower prices than in the United States. Obtaining coverage and adequate reimbursement for our product candidates may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. Similarly, because our product candidates are physician-administered injectables, separate reimbursement for the product itself may or may not be available. Instead, the administering physician may or may not be reimbursed for providing the treatment or procedure in which our product is used.

Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Third-party payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor-by-payor basis. One payor’s determination to provide coverage for a drug does not assure that other payors will also provide

coverage and adequate reimbursement for the drug. Additionally, a third-party payor's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal, and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future, including repeal, replacement, or significant revisions to the Affordable Care Act. The continuing efforts of the government, insurance companies, managed care organizations, and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and reimbursement approval for a product;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Additionally, we may develop companion diagnostic tests for use with our product candidates. If we develop such a companion diagnostic test, we, or our collaborators, may also seek to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement we seek for our product candidates, if approved. While we have not yet developed any companion diagnostic test for our product candidates, if we do, there is significant uncertainty regarding our ability to obtain coverage and adequate reimbursement for the same reasons applicable to our product candidates. Our inability to promptly obtain coverage and adequate reimbursement from both third-party payors for the product candidates and any companion diagnostic tests that we may develop and for which we obtain regulatory approval could have a material and adverse effect on our business, financial condition, results of operations, and prospects.

We face potential liability related to the privacy of health information we obtain from clinical trials sponsored by us or our collaborators, from research institutions and our collaborators, and directly from individuals.

We and our partners and vendors are subject to various federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address data privacy and security). If we fail to comply with these laws and regulations we may be subject to litigation, regulatory investigations, enforcement notices, enforcement actions, fines, and criminal or civil penalties, as well as negative publicity and a potential loss of business.

In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. For example, most healthcare providers, including research institutions from which we or our collaborators obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH. Under HIPAA, we could potentially face substantial criminal or civil penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information, or otherwise violate applicable HIPAA requirements related to the protection of such information. Even when HIPAA does not apply, failing to take appropriate steps to keep consumers' personal information secure may constitute a violation of the Federal Trade Commission Act.

In addition, we may maintain sensitive personally identifiable information, including health information, that we receive throughout the clinical trial process, in the course of our research collaborations, and directly from individuals (or their healthcare providers) who enroll in our patient assistance programs. As such, we may be subject to state laws requiring notification of affected individuals and state regulators in the event of a breach of personal information. These state laws include the recently enacted California Consumer Privacy Act, which establishes additional data privacy rights for residents of the State of California. Similar laws have been proposed in other states

and at the federal level, and if passed, such laws may have potentially conflicting requirements that would make compliance challenging.

Our clinical trial programs and research collaborations outside the United States may implicate international data protection laws, including, in Europe, the General Data Protection Regulation, or GDPR, which became effective in 2018. The GDPR imposes stringent operational requirements for processors and controllers of personal data. Among other things, the GDPR requires detailed notices for clinical trial subjects and investigators, as well as requirements regarding the security of personal data and notification of data processing obligations or security incidents to appropriate data protection authorities or data subjects. If our privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices, and/or enforcement actions requiring us to change the way we use personal data and/or fines. In addition to statutory enforcement, a personal data breach can lead to negative publicity and a potential loss of business. Further, following the United Kingdom's withdrawal from the E.U. effective as of December 31, 2020, we will have to comply with the GDPR and the GDPR as incorporated into United Kingdom national law, which may have differing requirements. If we fail to comply with United Kingdom data protection laws we may be subject to litigation, regulatory investigations, enforcement notices, and/or enforcement actions, as well as negative publicity and a potential loss of business.

We are also subject to evolving EEA laws on data export, as we may transfer personal data from the EEA to other jurisdictions. Recent legal developments in Europe have created complexity and uncertainty regarding transfers of personal data from the EEA to the United States. For example, on July 16, 2020, the Court of Justice of the European Union, or CJEU, invalidated the EU-US Privacy Shield Framework, or Privacy Shield, under which personal data could be transferred from the EEA to United States entities who had self-certified under the Privacy Shield scheme. Moreover, it is uncertain whether the standard contractual clauses will also be invalidated by the European courts or legislature. As government authorities issue further guidance on personal data export mechanisms and/or start taking enforcement action, we could suffer additional costs, complaints, and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results. These laws and regulations may apply, not only to us, but also to vendors that store or otherwise process data on our behalf, such as information technology vendors. If such a vendor misuses data we have provided to it, or fails to safeguard such data, we may be subject to litigation, regulatory investigations, enforcement notices, and/or enforcement actions, as well as negative publicity and a potential loss of business.

We are likely to be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend, and could result in adverse publicity that could harm our business. Moreover, even if we take all necessary action to comply with regulatory requirements, we could be subject to a hack or data breach, which could subject us to fines and penalties, as well as reputational damage.

If we or any collaborators fail to comply with applicable federal, state, or local regulatory requirements, we could be subject to a range of regulatory actions that could affect our or any collaborators' ability to seek to commercialize our clinical candidates. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business.

Risks Related to Commercialization of Our Product Candidates

We operate in highly competitive and rapidly changing industries, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.

The biotechnology and pharmaceutical industries are highly competitive and subject to significant and rapid technological change. Our success is highly dependent on our ability to discover, develop and obtain marketing approval for new and innovative products on a cost-effective basis and to market them successfully. In doing so, we face and will continue to face intense competition from a variety of businesses, including large pharmaceutical and biotechnology companies, academic institutions, government agencies and other public and private research

organizations. These organizations may have significantly greater resources than we do and conduct similar research, seek patent protection and establish collaborative arrangements for research, development, manufacturing, and marketing of products that compete with our product candidates. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries.

With the proliferation of new oncology drugs and therapies, we expect to face increasingly intense competition as new technologies become available. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. The highly competitive nature of and rapid technological changes in the biotechnology and pharmaceutical industries could render our product candidates or our technology obsolete, less competitive or uneconomical. Our competitors may, among other things:

- have significantly greater financial, manufacturing, marketing, drug development, technical, and human resources than we do;
- develop and commercialize products that are safer, more effective, less expensive, more convenient or easier to administer, or have fewer or less severe side effects;
- obtain quicker regulatory approval;
- establish superior proprietary positions covering our products and technologies;
- implement more effective approaches to sales and marketing; or
- form more advantageous strategic alliances.

Should any of these factors occur, our business, financial condition, and results of operations could be materially adversely affected.

In addition, any collaborators may decide to market and sell products that compete with the product candidates that we have agreed to license to them, and any competition by our collaborators could also have a material adverse effect on our future business, financial condition, and results of operations.

Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

If the market opportunity for any product candidate that we or our strategic partners develop is smaller than we believe, our revenue may be adversely affected and our business may suffer.

We intend to initially focus our product candidate development on treatments for various oncology indications. Our projections of addressable patient populations that may benefit from treatment with our product candidates are based on our estimates. These estimates, which have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, and market research, may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these cancers. Additionally, the potentially addressable patient population for our product candidates may not ultimately be amenable to treatment with our product candidates. Our market opportunity may also be limited by future competitor treatments that enter the market. If any of our estimates prove to be inaccurate, the market opportunity for any product candidate that we or our strategic partners develop could be significantly diminished and have an adverse material impact on our business.

The market opportunities for our product candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small.

Cancer therapies are sometimes characterized by line of therapy (first, second, third, fourth, etc.), and the FDA often initially approves new therapies only for use in a particular line or lines of therapy. When cancer is detected early enough, first line therapy is sometimes adequate to provide a cure or prolong life without a cure.

Whenever first line therapy (typically chemotherapy, hormone therapy, surgery, or a combination of these) proves unsuccessful, second line therapy (typically more chemotherapy, radiation, antibody drugs, tumor targeted small molecules, or a combination of these) may be administered. Third or fourth line therapies can include bone marrow transplantation, antibody and small molecule targeted therapies, more invasive forms of surgery, and new technologies. We may initially seek approval of our product candidates as a third line therapy for patients who have failed other approved treatments. Subsequently, for product candidates that prove to be sufficiently beneficial, if any, we would expect to seek approval as a second and first line therapy. However, there is no guarantee that our product candidates, even if initially approved, would be subsequently approved as a second or first line therapy. In addition, we may have to conduct additional clinical trials prior to gaining approval as a second or first line therapy. Because the potentially addressable patient target population for our product candidates may be limited to patients who are ineligible for or have failed prior treatments, even if we obtain significant market share for our product candidates, we may never achieve profitability.

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

Because we have limited financial and managerial resources, we focus on research programs, therapeutic platforms, and product candidates that we identify for specific indications. Additionally, we have contractual commitments under our collaboration agreements to use commercially reasonable efforts to develop certain programs and thus, do not have unilateral discretion to vary from such agreed to efforts. In addition, we have contractual commitments to conduct certain development plans, and thus may not have discretion to modify such development plans, including clinical trial designs, without agreement from our collaboration partners. As a result, we may forego or delay pursuit of opportunities with other therapeutic platforms or product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs, therapeutic platforms, and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing, or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

Even if approved, our products may not gain market acceptance, in which case we may not be able to generate product revenues, which will materially adversely affect our business, financial condition, and results of operations.

Even if the FDA or any other regulatory authority approves the marketing of any product candidates that we develop on our own or with a collaborator, physicians, healthcare providers, patients, or the medical community may not accept or use them. Additionally, the product candidates that we are developing are based on our proprietary ARC platform, which is a new technology. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenues or any profits from operations. The degree of market acceptance of any of our product candidates will depend on a variety of factors, including:

- the timing of market introduction;
- the terms of any approvals and the countries in which approvals are obtained;
- the number and clinical profile of competing products;
- our ability to provide acceptable evidence of safety and efficacy;
- the prevalence and severity of any side effects;
- relative convenience and ease of administration;
- cost-effectiveness;
- patient diagnostics and screening infrastructure in each market;
- marketing and distribution support;

- adverse publicity about our product candidates;
- availability of coverage, adequate reimbursement and sufficient payment from health maintenance organizations and other insurers, both public and private, for our product candidates, or the procedures utilizing our product candidates, if approved;
- the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors and government authorities; and
- other potential advantages over alternative treatment methods.

If our product candidates fail to gain market acceptance, this will have a material adverse impact on our ability to generate revenues to provide a satisfactory, or any, return on our investments. Even if some products achieve market acceptance, the market may prove not to be large enough to allow us to generate significant revenues.

We currently have no marketing, sales, or distribution infrastructure and we intend to either establish a sales and marketing infrastructure or outsource this function to a third party. Either of these commercialization strategies carries substantial risks to us.

We currently have no marketing, sales, and distribution capabilities because all of our product candidates are still in clinical or preclinical development. If any of our product candidates are approved, we intend to either establish a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our product candidates in a legally compliant manner, or to outsource this function to a third party. There are risks involved if we decide to establish our own sales and marketing capabilities or enter into arrangements with third parties to perform these services. To the extent that we enter into collaboration agreements with respect to marketing, sales or distribution, our product revenue may be lower than if we directly marketed or sold any approved products. Such collaborative arrangements with partners may place the commercialization of our products outside of our control and would make us subject to a number of risks including that we may not be able to control the amount or timing of resources that our collaborative partner devotes to our products or that our collaborator's willingness or ability to complete its obligations, and our obligations under our arrangements may be adversely affected by business combinations or significant changes in our collaborator's business strategy.

If we are unable to enter into these arrangements on acceptable terms or at all, we may not be able to successfully commercialize any approved products. If we are not successful in commercializing any approved products, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses, which would have a material adverse effect on our business, financial condition, and results of operations.

Our product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

The ACA includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a highly similar or "biosimilar" product may not be submitted to the FDA until four years following the date that the reference product was first approved by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first approved. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of their product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent

litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

Jurisdictions in addition to the United States have established abbreviated pathways for regulatory approval of biological products that are biosimilar to earlier approved reference products. For example, the European Union has had an established regulatory pathway for biosimilars since 2004. However, biosimilars can only be authorized once the period of data exclusivity on the reference biological medicine has expired.

The increased likelihood of biosimilar competition has increased the risk of loss of innovators' market exclusivity. Due to this risk, and uncertainties regarding patent protection, if our clinical candidates are approved for marketing, it is not possible to predict the length of market exclusivity for any particular product with certainty based solely on the expiration of the relevant patent(s) or the current forms of regulatory exclusivity. It is also not possible to predict changes in United States regulatory law that might reduce biological product regulatory exclusivity. The loss of market exclusivity for a product would likely materially and negatively affect revenues and we may not generate adequate or sufficient revenues from them or be able to reach or sustain profitability.

Risks Related to Our Dependence on Third Parties

We rely on third-parties to manufacture our product candidates. Any failure by a third-party manufacturer to produce acceptable drug substance for us or to obtain authorization from the FDA or comparable regulatory authorities may delay or impair our ability to initiate or complete our clinical trials, obtain regulatory approvals or commercialize approved products.

We do not currently own or operate any GMP manufacturing facilities nor do we have any in-house GMP manufacturing capabilities. We rely on our strategic partners to manufacture product candidates licensed to them or work with multiple third-party contract manufacturers to produce sufficient quantities of materials required for the manufacture of our product candidates for preclinical testing and clinical trials, in compliance with applicable regulatory and quality standards, and intend to do so for the commercial manufacture of our products, if approved. If we are unable to arrange for such third-party manufacturing sources, or fail to do so on commercially reasonable terms, we may not be able to successfully produce sufficient supply of product candidate or we may be delayed in doing so. Such failure or substantial delay could materially harm our business.

We rely on third parties for biological materials that are used in our discovery and development programs. These materials can be difficult to produce and occasionally have variability from the product specifications. Any disruption in the supply of these biological materials consistent with our product specifications could materially adversely affect our business. Although we have control processes and screening procedures, biological materials are susceptible to damage and contamination and may contain active pathogens. We may also have lower yields in manufacturing batches, which can increase our costs and slow our development timelines. Improper storage of these materials, by us or any third-party suppliers, may require us to destroy some of our biological raw materials or product candidates.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including reliance on the third party for regulatory compliance and quality control and assurance, volume production, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control (including a failure to synthesize and manufacture our product candidates in accordance with our product specifications) and the possibility of termination or nonrenewal of the agreement by the third party at a time that is costly or damaging to us.

In addition, the FDA and other regulatory authorities require that our product candidates be manufactured according to cGMPs and similar foreign standards relating to methods, facilities, and controls used in the manufacturing, processing, and packing of the product, which are intended to ensure that biological products are safe and that they consistently meet applicable requirements and specifications.

Pharmaceutical manufacturers are required to register their facilities and products manufactured at the time of submission of the marketing application and then annually thereafter with the FDA and certain state and foreign agencies. If the FDA or a comparable foreign regulatory authority does not approve our proposed contract manufacturer's facilities for the manufacture of our product candidates or if it withdraws any such approval in the

future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for, or market our product candidates, if approved. Any discovery of problems with a product, or a manufacturing or laboratory facility used by us or our strategic partners, may result in restrictions on the product or on the manufacturing or laboratory facility, including marketed product recall, suspension of manufacturing, product seizure, or a voluntary withdrawal of the drug from the market. We may have little to no control regarding the occurrence of third-party manufacturer incidents.

If we were unable to find an adequate replacement or another acceptable solution in time, our clinical trials could be delayed, or our commercial activities could be harmed. In addition, the fact that we are dependent on our collaborators, our suppliers, and other third parties for the manufacture, filling, storage, and distribution of our product candidates means that we are subject to the risk that the products may have manufacturing defects that we have limited ability to prevent or control. The sale of products containing such defects could adversely affect our business, financial condition, and results of operations. Any failure by our third-party manufacturers to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates.

Pharmaceutical manufacturers are also subject to extensive post-marketing oversight by the FDA and comparable regulatory authorities in the jurisdictions where the product is marketed, which include periodic unannounced and announced inspections by the FDA to assess compliance with cGMP requirements. If an FDA inspection of a manufacturer's facilities reveals conditions that the FDA determines not to comply with applicable regulatory requirements, the FDA may issue observations through a Notice of Inspectional Observations, commonly referred to as a "Form FDA 483" report. If observations in the Form FDA 483 report are not addressed in a timely manner and to the FDA's satisfaction, the FDA may issue a Warning Letter or proceed directly to other forms of enforcement action. Any failure by one of our contract manufacturers to comply with cGMP or to provide adequate and timely corrective actions in response to deficiencies identified in a regulatory inspection could result in further enforcement action that could lead to a shortage of products and harm our business, including withdrawal of approvals previously granted, seizure, injunction or other civil or criminal penalties. The failure of a manufacturer to address any concerns raised by the FDA or foreign regulators could also lead to plant shutdown or the delay or withholding of product approval by the FDA in additional indications, or by foreign regulators in any indication. Certain countries may impose additional requirements on the manufacturing of drug products or drug substances, and on manufacturers, as part of the regulatory approval process for products in such countries. The failure by our third-party manufacturers to satisfy such requirements could impact our ability to obtain or maintain approval of our products in such countries.

We rely, and expect to continue to rely, on third parties, including independent clinical investigators and CROs, to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements, or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators and third-party CROs, to conduct our preclinical studies and clinical trials and to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our products candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators, and trial sites. If we or any of our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with

product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

Further, these investigators and CROs are not our employees and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to our product candidates and clinical trials. If independent investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of any product candidates that we develop. In addition, the use of third-party service providers may require us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors, or if we are liquidated.

There is a limited number of third-party service providers that specialize or have the expertise required to achieve our business objectives. If any of our relationships with these third-party laboratories, CROs or clinical investigators terminate, we may not be able to enter into arrangements with alternative laboratories, CROs, or investigators or to do so in a timely manner or on commercially reasonable terms. If laboratories, CROs, or clinical investigators do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our preclinical or clinical protocols, regulatory requirements or for other reasons, our preclinical or clinical trials may be extended, delayed, or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenues could be delayed. Switching or adding additional laboratories or CROs (or investigators) involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new laboratory or CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Additionally, CROs may lack the capacity to absorb higher workloads or take on additional capacity to support our needs. Though we carefully manage our relationships with our contracted laboratories and CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition, and prospects.

In addition, clinical investigators 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 the FDA concludes that the financial relationship may have affected the interpretation of the preclinical study or clinical trial, the integrity of the data generated at the applicable preclinical study or clinical trial site may be questioned and the utility of the preclinical study or clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA. Any such delay or rejection could prevent us from commercializing our clinical-stage product candidate or any future product candidates.

We may not realize the benefits of any existing or future collaborative or licensing arrangement, and if we fail to enter into new strategic relationships our business, financial condition, commercialization prospects, and results of operations may be materially adversely affected.

Our product development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. Therefore, for some of our product candidates, we may decide to enter into new collaborations with pharmaceutical or biopharmaceutical companies for the development and potential commercialization of those product candidates. For instance, we have a discovery collaboration with Takeda pursuant to which we are collaborating on the development of certain product candidates, we are obligated to conduct certain development activities, and pursuant to which Takeda has an option to acquire a commercial license to these product candidates.

We face significant competition in seeking appropriate collaborators. Collaborations are complex and time-consuming to negotiate and document. We may also be restricted under existing and future collaboration agreements

from entering into agreements on certain terms with other potential collaborators. We may not be able to negotiate collaborations on acceptable terms, or at all. If our strategic collaborations do not result in the successful development and commercialization of product candidates, or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. Moreover, our estimates of the potential revenue we are eligible to receive under our strategic collaborations may include potential payments related to therapeutic programs for which our collaborators have discontinued development or may discontinue development in the future. If that were to occur, we may have to curtail the development of a particular product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of our sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we will not be able to bring our product candidates to market and generate product revenue.

In instances where we do enter into collaborations, we could be subject to the following risks, each of which may materially harm our business, commercialization prospects, and financial condition:

- we may not be able to control the amount and timing of resources that is required of us to complete our development obligations or that the collaboration partner devotes to the product development or marketing programs;
- the collaboration partner may experience financial difficulties;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
- we may be required to relinquish important rights such as marketing, distribution, and intellectual property rights;
- 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;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- a collaborator could move forward with a competing product developed either independently or in collaboration with third parties, including our competitors;
- we and our collaboration partner may disagree regarding the development plan for product candidates on which we are collaborating (for example, we may disagree with a collaboration partner regarding target indications, inclusion or exclusion criteria for a clinical trial, or the decision to seek front line therapy approval versus second, third, or fourth line therapy approval);
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources;
- business combinations or significant changes in a collaborator’s business strategy may adversely affect our willingness to complete our obligations under any arrangement; or
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.

If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the results, revenue, or specific net income that justifies such transaction.

To date, we have relied on one single-source supplier for bulk drug substance. The loss of this supplier or its failure to supply us with BDS on a timely basis could cause our inability to develop our product candidates and adversely affect our business.

We depend on one single-source supplier for bulk drug substance, or BDS. Although we believe that we have a substantial reserve of BDS to support our current clinical trial programs, there can be no assurance that our supply of BDS will not be limited, interrupted, or of satisfactory quality or continue to be available at acceptable prices. Additionally, we do not have any control over the process or timing of the acquisition or manufacture of materials by our supplier, and cannot ensure that it will deliver to us the BDS we order on time, or at all. The loss of BDS provided by this supplier could require us to change the design of our product candidate development process based on the functions, limitations, features, and specifications of the replacement.

In addition, the lead time needed to establish a relationship with a new supplier can be lengthy, and we may experience delays in meeting demand in the event we must switch to a new supplier. The time and effort to qualify a new supplier could result in additional costs, diversion of resources, or reduced manufacturing yields, any of which would negatively impact our operating results. Our reliance on this single-source supplier exposes us to certain risks, including the following:

- our supplier may cease or reduce production or deliveries, raise prices, or renegotiate terms;
- we may be unable to locate a suitable replacement on acceptable terms or on a timely basis, if at all;
- if there is a disruption to our single-source supplier's operations, and if we are unable to enter into arrangements with alternative suppliers, we may need to halt our clinical trial programs;
- delays caused by supply issues may harm our reputation, frustrate our customers, and cause them to turn to our competitors for future projects; and
- our ability to develop our product candidates could be materially and adversely impacted if the single-source supplier upon which we rely were to experience a significant business challenge, disruption or failure due to issues such as financial difficulties or bankruptcy, issues relating to other customers such as regulatory or quality compliance issues, or other financial, legal, regulatory, or reputational issues.

Moreover, to meet anticipated demand, our single-source supplier may need to increase manufacturing capacity, which could involve significant challenges. This may require us and our supplier to invest substantial additional funds and hire and retain the technical personnel who have the necessary experience. Neither we nor our supplier may successfully complete any required increase to existing manufacturing capacity in a timely manner, or at all.

If we are unable to obtain sufficient raw and intermediate materials on a timely basis or if we experience other manufacturing or supply difficulties, our business may be adversely affected.

The manufacture of certain of our product candidates requires the timely delivery of sufficient amounts of raw and intermediate materials. We work closely with our suppliers to ensure the continuity of supply, but cannot guarantee these efforts will always be successful. Further, while efforts are made to diversify our sources of raw and intermediate materials, in certain instances we acquire raw and intermediate materials from a sole supplier. While we believe that alternative sources of supply exist where we rely on sole supplier relationships, there can be no assurance that we will be able to quickly establish additional or replacement sources for some materials. A reduction or interruption in supply, and an inability to develop alternative sources for such supply, could adversely affect our ability to manufacture our product candidates in a timely or cost-effective manner.

Supply sources could be interrupted from time to time and, if interrupted, there is no guarantee that supplies could be resumed within a reasonable time frame and at an acceptable cost or at all.

We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical trials. There are a limited number of suppliers for raw materials that we use to manufacture our drugs and there may be a need to assess alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidates for our clinical trials, and if approved, ultimately for commercial sale. We do not have any control over the process or timing of the acquisition of these raw materials by our manufacturers. Moreover, we currently do not have any agreements for the commercial

production of these raw materials. We cannot be sure that these suppliers will remain in business, or that they will not be purchased by one of our competitors or another company that is not interested in continuing to produce these materials for our intended purpose. In addition, the lead time needed to establish a relationship with a new supplier can be lengthy, and we may experience delays in meeting demand in the event a new supplier must be used. The time and effort to qualify a new supplier could result in additional costs, diversion of resources, or reduced manufacturing yields, any of which would negatively impact our operating results. Although we generally do not begin a clinical trial unless we believe we have a sufficient supply of a product candidate to complete the clinical trial, any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing, and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates.

Risks Related to Intellectual Property and Information Technology

We rely on patents and other intellectual property rights to protect our technology, including product candidates and our ARC and GADLEN platforms, the prosecution, enforcement, defense, and maintenance of which may be challenging and costly. Failure to protect or enforce these rights adequately could harm our ability to compete and impair our business.

Our commercial success depends in part on obtaining and maintaining patents and other forms of intellectual property rights for technology related to our product candidates, including, but not limited to, our ARC and GADLEN platforms, product candidates, methods used to manufacture those product candidates, formulations thereof, and the methods for treating patients using those product candidates. Given that the development of our technology and product candidates is at an early stage, our intellectual property portfolio with respect to certain aspects of our technology and product candidates is also at an early stage. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel platform technologies and product candidates that are important to our business. The patent prosecution process is expensive and time-consuming, and we may not be able to prepare, file, and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, during the patent prosecution process, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections.

The issuance, scope, validity, enforceability, and commercial value of our current or future patent rights are highly uncertain. It is possible that we will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Our pending and future patent applications may not result in patents being issued which protect our technology or product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and product candidates. The patent examination process may require us to narrow the scope of the claims of our pending and future patent applications, which may limit the scope of patent protection that may be obtained. Further, even if we obtain patents with sufficient scope to protect our technology or product candidates in their present forms, future technical changes to our technology or product candidates may render the patent coverage inadequate.

We cannot assure you that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it can invalidate or narrow the scope of a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue and even if such patents cover our product candidates, third parties may initiate opposition, interference, re-examination, post-grant review, *inter partes* review, nullification, or derivation actions in court or before patent offices, or similar proceedings challenging the validity, ownership, enforceability, or scope of such patents, which may result in the patent claims being narrowed, invalidated, or held unenforceable or circumvented. Because patent applications in the United States and other jurisdictions are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file any patent applications related to such inventions. Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover the technology. Furthermore, even where

we have a valid and enforceable patent, we may not be able to exclude others from practicing our invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license. Additionally, our competitors or other third parties may be able to evade our patent rights by developing new antibodies, biosimilar antibodies, or alternative technologies or products in a non-infringing manner.

In addition, 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. Moreover, some of our owned and in-licensed patents and patent applications may in the future be, co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we or our licensors may need the cooperation of any such co-owners of our owned and in-licensed patents in order to enforce such patents against third parties, and such cooperation may not be provided to us or our licensors. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other provisions during the patent application process. 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. The standards applied by the USPTO, foreign patent offices and patent courts or other authorities in granting patents and ruling on claim scope and validity are not always applied uniformly or predictably. Patent positions of life sciences companies can be uncertain and involve complex factual, scientific, and legal questions. Changes in either the patent laws or their interpretation in any jurisdiction that we seek patent protection may diminish our ability to protect our inventions, maintain and enforce our intellectual property rights; and, more generally, may affect the value of our intellectual property, including the narrowing of the scope of our patents and any that we may license.

Failure to protect or to obtain, maintain or extend adequate patent and other intellectual property rights could materially adversely affect our ability to develop and market our product candidates.

We may become involved in lawsuits to protect or enforce our issued patents relating to one or more of our product candidates or our proprietary platforms, including our ARC and GADLEN platforms, which could ultimately render our patents invalid or unenforceable and adversely affect our competitive position. Intellectual property litigation or other legal proceedings could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Competitors may infringe our patents or other intellectual property that relate to our ARC and GADLEN platforms and product candidates, their respective methods of use, manufacture, and formulations thereof. To protect our competitive position and counter infringement or unauthorized use, we may from time to time need to resort to litigation to enforce or defend any patents or other intellectual property rights owned or licensed by us by filing infringement claims. As enforcement of intellectual property rights is difficult, unpredictable, time-consuming, and expensive, we may fail in enforcing our rights, in which case our competitors may be permitted to use our technology without being required to pay us any license fees. In addition, litigation involving our patents carries the risk that one or more of our patents will be held invalid (in whole or in part, on a claim-by-claim basis) or held unenforceable. Such an adverse court ruling could allow third parties to commercialize our product candidates or methods, or our ARC or GADLEN platform, and then compete directly with us, without payment to us.

Even if resolved in our favor, such litigation and other legal proceedings may cause us to incur significant expenses and would be likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities, and may impact our reputation. 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 our resources available for development activities. We may not have sufficient financial

or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

If we were to initiate legal proceedings against a third party to enforce a patent related to one of our product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the United States or in certain jurisdictions in Europe, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, novelty, non-obviousness, written description or enablement. Grounds for an unenforceability assertion could be 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 invalidity and/or unenforceability claims before administrative bodies in the United States or abroad, even outside the context of litigation through opposition, interference, re-examination, post-grant review, *inter partes* review, nullification, or derivation actions or proceedings. The outcome following legal assertions of invalidity and unenforceability during patent litigation or administrative proceedings is unpredictable. 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 one or more of our technologies, product candidates, methods or certain aspects of our ARC or GADLEN platform. Such a loss of patent protection could have a material adverse impact on our business.

There is also a risk that, even if the validity of our patents is upheld, the court will construe our patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover our own products or the other party's products. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. Patents and other intellectual property rights also will not protect our technology if competitors design around our protected technology without infringing our patents or other intellectual property rights.

We may fail to identify relevant third-party patents or may incorrectly interpret the relevance, scope, or expiration of a third-party patent which might adversely affect our ability to develop our ARC and GADLEN platforms and product candidates.

We cannot guarantee that our operations and activities do not, or will not in the future, infringe existing or future patents. We also cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to our ARC or GADLEN platform or necessary for the commercialization of our product candidates in any jurisdiction.

Numerous U.S. and foreign patents and pending patent applications exist in our market that are owned by 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 are issued. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, and 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 thereof. As such, there may be applications of third parties 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 product candidates.

The scope of a patent claim is determined by an interpretation of law and, among other considerations, the written disclosure in a patent and the patent's prosecution history. The claim scope sought in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted or further altered even after patent issuance, including through interferences, post-grant proceedings, opposition proceedings, or other intellectual property proceedings to address issues or errors that may render claims of the issued patent either wholly or partially invalid or unenforceable. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates. We may incorrectly determine that our product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending 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 product candidates. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, including our platform technologies, product candidates and their respective methods of use, manufacture, and formulations thereof, and could result in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

Intellectual property rights of third parties could adversely affect our ability to develop or commercialize our product candidates, such that we could be required to litigate or obtain licenses from third parties in order to develop or market our product candidates.

Our commercial success depends, in part, on our ability to develop, manufacture, market, and sell our product candidates without infringing, or otherwise violating the intellectual property and other proprietary rights of third parties. Our competitive position may suffer if patents issued to third parties or other third-party intellectual property rights cover our methods or product candidates or elements thereof, our manufacture or uses relevant to our development plans, our product candidates or other attributes of our product candidates, or our ARC or GADLEN platform. In such cases, we may not be in a position to develop or commercialize product candidates unless we successfully pursue litigation to nullify or invalidate the third-party intellectual property right concerned, which can be expensive and time-consuming, or have to enter into a license agreement with the intellectual property right holder, if available on commercially reasonable terms at all.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our product candidates. Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. For example, we are aware of a patent application recently allowed in the United States that, when issued, may impact our competitive position with respect to SL-172154. While we believe that the allowed claims may not be valid and that they may be reasonably challenged for validity, there can be no assurance that any such challenge would be successful, in which case we may be required to obtain a license in order to commercialize our product candidate, if approved.

If we are sued for patent infringement, we would need to demonstrate that our product candidates or platform technologies either do not infringe the patent claims of a relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity may be difficult. For example, in the United States, proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. We may not have sufficient resources to bring these actions to a successful conclusion. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage or continue costly, unpredictable, and time-consuming litigation and may be prevented from or experience substantial delays in marketing our product candidates.

Our involvement in litigation, and in any interferences, post-grant proceedings, opposition proceedings, or other intellectual property proceedings inside and outside of the United States may divert management from focusing on business operations, and even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on our business and operations. In addition, 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.

Any current and potential intellectual property litigation also could force us to do one or more of the following:

- stop marketing, selling, incorporating, manufacturing, or using our product candidates or any products, if approved, in the United States and/or other jurisdictions that use the subject intellectual property;
- obtain from a third party asserting its intellectual property rights, a license to sell or use the relevant technology, including the obligation to pay royalties, which license may not be available on reasonable terms, or at all, or may be non-exclusive thereby giving our competitors access to the same technologies licensed to us;
- redesign those products or processes that use any allegedly infringing or misappropriated technology, which may result in significant cost or delay to us, or which redesign could be impossible or technically infeasible; or
- pay damages, including the possibility of treble damages and attorneys' fees in a patent case if a court finds us to have willfully infringed certain intellectual property rights.

We may need to obtain additional licenses of third-party technology that may not be available to us or are available only on commercially unreasonable terms, and which may cause us to operate our business in a more costly or otherwise adverse manner that was not anticipated.

We own and are pursuing rights to the intellectual property, including patent applications relating to our ARC platform and our product candidates. From time to time, we may be required to license technologies relating to our therapeutic research programs from additional third parties to further develop or commercialize our platform technologies and product candidates. The targets of our product candidates have also been the subject of research by many companies that have filed patent applications or have patents related to such targets and therapeutic methods relating to those targets. There can be no assurance any such patents will not be asserted against us or that we will not need to seek licenses from such third parties. We may not be able to secure such licenses on acceptable terms, if at all, and any such litigation would be costly and time-consuming.

Should we be required to obtain licenses to any third-party technology, including any such patents required to manufacture, use, or sell our product candidates, the growth of our business will likely depend in part on our ability to acquire, in-license, maintain, or use these proprietary rights. The inability to obtain any third-party license required to develop or commercialize any of our product candidates could cause us to abandon any related efforts, which could seriously harm our business and operations.

In addition, our product candidates may require specific formulations to work effectively and efficiently and the rights to these formulations may be held by others. 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. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. If we are unable to successfully obtain a license to third-party intellectual property rights necessary for the development of a product candidate or program, we may have to abandon development of that product candidate or program and our business and financial condition could suffer.

We depend on intellectual property licensed from third parties and if we fail to comply with our obligations under any license, collaboration or other agreements, we may be required to pay damages and could lose intellectual

property rights that are necessary for developing and protecting our product candidates or we could lose certain rights to grant sublicenses.

Our current licenses impose, and any future licenses we enter into are likely to impose, various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement, and/or other obligations on us. If we breach any of these obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture, and sell any future products that are covered by the licensed technology or enable a competitor to gain access to the licensed technology. 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 determine currently 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.

Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our product candidates, 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 under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

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

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 by potential collaborators, partners, or

customers in our markets of interest. 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. If other entities use trademarks similar to ours in different jurisdictions, or have senior rights to ours, it could interfere with our use of our current trademarks throughout the world.

During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in both the USPTO and comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, which may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

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

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

If we do not obtain protection under the Hatch-Waxman Amendments and similar non-U.S. legislation for extending the term of patents covering each of our product candidates, our business may be materially harmed.

Depending upon the timing, duration, and conditions of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and similar legislation in the European Union. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. 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 claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents, or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced, possibly materially.

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

Patents are of national or regional effect. While we will endeavor to try to protect our technologies, products and product candidates with intellectual property rights such as patents throughout the world, as appropriate, the process of obtaining patents is time-consuming, expensive, and sometimes unpredictable in other countries. We may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent rights at a commercially

reasonable cost or in a timely manner. In addition, we may not pursue or obtain patent protection in all markets. As such, 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.

International applications under the Patent Cooperation Treaty, or PCT, are usually filed within 12 months after the priority filing. Based on the PCT filing, national and regional patent applications may be filed in additional jurisdictions where we believe our product candidates may be marketed. We have not, and will not, file for patent protection in all national and regional jurisdictions where such protection may be available. Filing, prosecuting, and defending patents on all of our research programs and product candidates in all countries throughout the world would be prohibitively expensive, and, therefore, the scope and strength of our intellectual property rights will vary from jurisdiction to jurisdiction. In addition, we may decide to abandon national and regional patent applications before grant. Finally, the grant proceeding of each national/regional patent is an independent proceeding which may lead to situations in which applications might in some jurisdictions be refused by the relevant patent offices, while granted by others. Further, the standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. It is common that depending on the country, the scope of patent protection may vary for the same product candidate and/or technology. As such, we do not know the degree of future protection that we will have on our technologies and product candidates in different jurisdictions.

Competitors may use our or our collaboration partners' 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 or our collaboration partners 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 or our collaboration partners' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

The laws of some jurisdictions, particularly certain developing countries, do not protect intellectual property rights, particularly those relating to pharmaceuticals or biologics, to the same extent as laws in the United States, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. 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. If we encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition from others in those jurisdictions.

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 significant commercial advantage from the intellectual property that we develop or license.

Some countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired and our business and results of operations may be adversely affected.

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

We generally enter into confidentiality and intellectual property assignment agreements with our employees, consultants, and contractors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, those agreements may not be honored and may not effectively assign intellectual property rights to us. Moreover, there may be some circumstances, where we are unable to negotiate for such ownership rights. Disputes regarding ownership or inventorship of intellectual

property can also arise in other contexts, such as collaborations and sponsored research. If we are subject to a dispute challenging our rights in or to patents or other intellectual property, such a dispute could be expensive and time consuming. If we were unsuccessful, we could lose valuable rights in intellectual property that we regard as our own. In addition, interferences, post-grant proceedings, opposition proceedings, derivation proceedings, or other intellectual property 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.

The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The following examples are illustrative:

- others may be able to make product candidates similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- the patents of third parties may have an adverse effect on our business;
- we or any future strategic partners might not have been the first to conceive or reduce to practice the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or any future strategic partners 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, misappropriating, or otherwise violating 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 not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- we cannot predict the degree and range of protection any issued patents will afford us against competitors, whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications, or whether we will need to initiate litigation or administrative proceedings which may be costly whether we win or lose;
- 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;
- third parties performing manufacturing or testing for us using our product candidates or technologies could use the intellectual property of others without obtaining a proper license; and
- we may not develop additional technologies that are patentable.

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

Composition of matter patents for biological and pharmaceutical products such as our product candidates are generally considered to be the strongest form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. We cannot be certain that the claims in our pending patent applications covering composition of matter of our product candidates will be considered patentable by the USPTO or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered valid and enforceable by courts in the United States or foreign countries. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products "off-label." Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological complexity and legal complexity. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time-consuming, and inherently uncertain.

In September 2011, the America Invents Act, or the AIA, was enacted in the United States, resulting in significant changes to the U.S. patent system. An important change introduced by the AIA was a transition to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention, which went into effect on March 16, 2013. Therefore, a third party that now files a patent application in the USPTO before we do could be awarded a patent covering an invention of ours even if we created the invention before it was created by the third party. While we are cognizant of the time from invention to filing of a patent application, circumstances could prevent us from promptly filing patent applications for our inventions.

Among some of the other changes introduced by the AIA were changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U.S. patents. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. The AIA and its continued implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications, and the patent applications of our collaborators, and the enforcement or defense of our issued patents.

Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, in the case, *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, the U.S. Supreme Court held that certain claims to DNA molecules are not patentable. While we do not believe that any of the patents owned or licensed by us will be found invalid based on this decision, we cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents. Similarly, there is complexity and uncertainty related to European patent laws. For example, European patent laws are stringent in the type of amendments that are allowed during prosecution, and the complexity and uncertainty of European patent laws has also increased in recent years. These limitations and requirements could adversely affect our ability to obtain new patents in the future that may be important for our business.

We may rely on trade secret and proprietary know-how, which can be difficult to trace and enforce and, if we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and product candidates, we may rely on trade secrets and/or confidential know-how to protect our technology, especially where patent protection is believed to be of limited value, to maintain our competitive position with respect to our research programs and product candidates. Elements of our product candidates, including processes for their preparation and manufacture, may involve proprietary know-how, information, or technology that is not covered by patents, and thus for these aspects we may consider trade secrets and know-how to be our primary intellectual property. Any disclosure, either intentional or unintentional, by our employees or by other third parties of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus adversely eroding our competitive position in our market.

Trade secrets and/or confidential know-how can be difficult to protect or maintain as confidential. To protect this type of information against disclosure or appropriation by competitors, we generally require our employees, consultants, contractors, collaborators, advisors, and other third parties to enter into confidentiality agreements with us. Despite these efforts, any of these parties may unintentionally or willfully breach the agreements and disclose our confidential information, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Enforcing a claim that a third party obtained illegally and is using trade secrets and/or confidential know-how is also expensive, time-consuming, and unpredictable.

The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction. The laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. Furthermore, if a competitor lawfully obtained or independently developed any of our trade secrets, 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. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, some courts inside and outside the United States are less willing or are unwilling to protect trade secrets or other proprietary information.

Trade secrets can 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 employees, consultants, contractors, collaborators, advisors, and other third parties to publish data potentially relating to our trade secrets, our agreements may contain certain limited publication rights. Because from time to time we expect to rely on third parties in the development, manufacture, and distribution of our product candidates 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 our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be harmed.

In addition, our competitors may independently develop substantially equivalent trade secrets, proprietary information, or know-how and may even apply for patent protection in respect of the same. If successful in obtaining such patent protection, our competitors could limit our use of our trade secrets and/or confidential know-how. Under certain circumstances and to make it more likely that we have our freedom to operate, we may also decide to publish some know-how to make it difficult for others to obtain patent rights covering such know-how, at the risk of potentially exposing our trade secrets to our competitors.

We may be subject to third-party claims asserting that our employees, consultants, contractors, collaborators, or advisors have misappropriated or wrongfully used or disseminated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees, including our senior management, were previously employed at universities or at other biopharmaceutical companies, including our competitors or potential competitors. Some of these employees executed proprietary rights, non-disclosure, and non-competition agreements in connection with such previous employment. Similarly, we work with consultants, contractors, collaborators, advisors, or other third parties who have worked with, and do currently work with, other companies, including our competitors or potential competitors, and have executed proprietary rights, non-disclosure, and non-competition agreements in connection with such other companies. Although we try to ensure that our employees, consultants, contractors, collaborators, advisors, or other third parties do not use or disclose the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees or individuals that we work with have used or disclosed confidential information or intellectual property of others, including trade secrets or other proprietary information, or that we caused an individual to breach the terms of his or her non-competition or non-solicitation agreement with a current or former employer or competitor.

Litigation may be necessary to defend against these claims and, even if we are successful, could result in substantial costs and could be a distraction to management, our employees, and our routine business. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to develop or commercialize our technology or product candidates. Such a license may not be available on commercially reasonable terms or at all. Moreover, any such litigation or the threat thereof may adversely affect our reputation and our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations, and financial condition.

Obtaining and maintaining our 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 noncompliance with these requirements.

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents within prescribed time limits. If we fail to maintain the patents and patent applications covering our product candidates or if we otherwise allow our patents or patent applications to be abandoned or lapse, our competitors might be able to enter the market, which would have an adverse effect on our business.

Our information technology systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches, which could adversely affect our business.

We collect and maintain information in digital form that is necessary to conduct our business, and we are dependent on our information technology systems and those of third parties to operate our business. 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, and data to comply with cGMP and data integrity requirements. It is critical that we do so in a secure manner to maintain data security and data integrity of such information. We have established physical, electronic, and organizational measures to safeguard and secure our systems to prevent a data compromise. 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. Despite the implementation of security measures, our information technology systems and data and those of our current or future CROs or other contractors and consultants are vulnerable to compromise or damage from computer hacking, malicious software, fraudulent activity, employee misconduct, human error, telecommunication and electrical failures, natural disasters, or other cybersecurity attacks or accidents. Future

acquisitions could expose us to additional cybersecurity risks and vulnerabilities from any newly acquired information technology infrastructure. Cybersecurity attacks are constantly increasing in sophistication and are made by groups and individuals with a wide range of motives (including industrial espionage) and expertise, including by organized criminal groups, "hacktivists," nation states, and others. As a company with an increasingly global presence, our systems are subject to frequent attacks and have been targeted by foreign actors for purposes of economic espionage. Due to the nature of some of these attacks, there is a risk that an attack may remain undetected for a period of time. While we continue to make investments to improve the protection of data and information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches.

Any cybersecurity incident could adversely affect our business, by leading to, for example, the loss of trade secrets or other intellectual property, demands for ransom or other forms of blackmail, or the unauthorized disclosure of personal or other sensitive information of our employees, clinical trial patients, customers, and others. Although to our knowledge we have not experienced any material cybersecurity incident to date, if such an event were to occur, it could seriously harm our development programs and our business operations. We could be subject to regulatory actions taken by governmental authorities, litigation under laws that protect the privacy of personal information, or other forms of legal proceedings, which could result in significant liabilities or penalties. Further, a cybersecurity incident may disrupt our business or damage our reputation, which could have a material adverse effect on our business, prospects, operating results, share price, stockholder value, and financial condition. We could also incur substantial remediation costs, including the costs of investigating the incident, repairing or replacing damaged systems, restoring normal business operations, implementing increased cybersecurity protections, and paying increased insurance premiums.

Risks Related to Ownership of Our Common Stock

Our stock price may be volatile or may decline regardless of our operating performance, resulting in substantial losses for investors.

The market price of our common stock may be highly volatile and may fluctuate substantially as a result of a variety of factors, some of which are related in complex ways. The market price of our common stock may fluctuate significantly in response to numerous factors, many of which are beyond our control, including the factors listed below and other factors described in this "Risk Factors" section:

- the commencement, enrollment, or results of current and future preclinical studies and clinical trials and trials we may conduct, or changes in the development status of our product candidates;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including, without limitation, the issuance by the FDA of a "refusal to file" letter or a request for additional information;
- adverse results or delays in clinical trials;
- our decision to initiate a preclinical study or clinical trial, not to initiate a preclinical study or clinical trial or to terminate an existing preclinical study or clinical trial;
- adverse actions taken by regulatory agencies with respect to our preclinical studies or clinical trials, manufacturing supply chain or sales and marketing activities, including failure to receive regulatory approval of our product candidates;
- changes in laws or regulations, including, but not limited to, nonclinical study or clinical trial requirements for approvals;
- any adverse changes to our relationship with manufacturers or suppliers;
- manufacturing, supply or distribution shortages;
- our failure to commercialize our product candidates;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates;

- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- variations in our results of operations;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or immuno-oncology in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- announcements made by us or our competitors of new product and service offerings, acquisitions, strategic relationships, joint ventures, or capital commitments;
- our inability to establish collaborations, if needed;
- our ability to effectively manage our growth;
- the size and growth of our initial cancer target markets;
- our ability to successfully treat additional types of cancers or at different stages;
- changes in the market valuations of similar companies;
- press reports, whether or not true, about our business;
- sales or perceived potential sales of our common stock by us or our stockholders in the future;
- overall fluctuations in the equity markets;
- ineffectiveness of our internal controls;
- changes in accounting practices or principles;
- changes or developments in the global regulatory environment;
- litigation involving us, our industry or both, or investigations by regulators into our operations or those of our competitors;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and The Nasdaq Stock Market, or Nasdaq, and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results, or financial condition. Additionally, the dramatic increase in the cost of directors' and officers' liability insurance may cause us to opt for lower overall policy limits or to forgo insurance that we may otherwise rely on to cover significant defense costs, settlements, and damages awarded to plaintiffs.

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

As of November 1, 2020, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 33.6% of our outstanding voting stock. Therefore, these stockholders 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, amendments of our organizational documents, 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 our common stock in the public market could cause our common stock price to fall.

Our common stock price could decline as a result of sales of a large number of shares of common stock or the perception that these sales could occur. These sales, or the possibility that these sales may occur, might also make it more difficult for us to sell equity securities in the future at a time and price that we deem appropriate.

Certain holders of our outstanding shares, of our common stock have rights, subject to some conditions, to require us to file registration statements covering the sale of their shares or to include their shares in registration statements that we may file for ourselves or our other stockholders. We have also registered the offer and sale of all shares of common stock that we may issue under our equity compensation plans and, as a result, these shares will be able to be sold in the public market upon issuance.

In addition, in the future, we may issue additional shares of common stock, or other equity or debt securities convertible into common stock, in connection with a financing, acquisition, employee arrangement, or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause the price of our common stock to decline.

If securities or industry analysts either do not publish research about us or publish inaccurate or unfavorable research about us, our business or our market, or if they change their recommendations regarding our common stock adversely, the trading price or trading volume of our common stock could decline.

The trading market for our common stock depends in part upon research and reports that securities or industry analysts may publish about us, our business, our market, or our competitors. If one or more of these analysts initiate research with an unfavorable rating or downgrade our common stock, provide a more favorable recommendation about our competitors or publish inaccurate or unfavorable research about our business, our common stock price would likely decline. If any analyst who may cover us were to cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause the trading price or trading volume of our common stock to decline.

We are an emerging growth company, and any decision on our part to comply only with certain reduced reporting and disclosure requirements applicable to emerging growth companies could make our common stock less attractive to investors.

We are an “emerging growth company” as defined in the JOBS Act and, for as long as we continue to be an emerging growth company, we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies but not to emerging growth companies, including:

- not being required to have our independent registered public accounting firm audit our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act;
- reduced disclosure obligations regarding executive compensation in our periodic reports and annual report on Form 10-K; and
- exemptions from the requirements of holding non-binding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved.
- We could be an emerging growth company for up to five years. Our status as an emerging growth company will end as soon as any of the following takes place:
- the last day of the fiscal year in which we have more than $1.07 billion in annual revenue;
- the date we qualify as a “large accelerated filer,” with at least $700 million of equity securities held by non-affiliates;
- the date on which we have issued, in any three-year period, more than $1.0 billion in non-convertible debt securities; or

- the last day of the fiscal year ending after the fifth anniversary of the completion of our initial public offering.

We cannot predict if investors will find our common stock less attractive if we choose to rely on any of the exemptions afforded to emerging growth companies. If some investors find our common stock less attractive because we rely on any of these exemptions, there may be a less active trading market for our common stock and the market price of our common stock may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, these financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

The requirements of being a public company may strain our resources, result in more litigation, and divert management's attention.

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

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

These new rules and regulations may make it more expensive for us to obtain director and officer liability insurance and, in the future, we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our Board, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

By disclosing information in this and in future filings required of a public company, our business and financial condition will become more visible, which we believe may result in threatened or actual litigation, including by competitors and other third parties. If those claims are successful, our business could be seriously harmed. Even if the claims do not result in litigation or are resolved in our favor, the time and resources needed to resolve them could divert our management's resources and seriously harm our business.

If we fail to maintain proper and effective internal controls over financial reporting our ability to produce accurate and timely financial statements could be impaired.

Pursuant to Section 404 of the Sarbanes-Oxley Act, our management will be required to report upon the effectiveness of our internal control over financial reporting beginning with the annual report for our fiscal year ending December 31, 2021. When we lose our status as an "emerging growth company" and a "smaller reporting company" and become an "accelerated filer" or a "large accelerated filer," our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Securities Exchange Act of 1934, as amended, or the Exchange Act, we have implemented and will continue to implement additional financial and management controls, reporting systems and procedures and we have hired and will continue to hire additional accounting and finance staff.

We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations, or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC, or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. We have designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make a required related party transaction disclosure. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

We do not currently intend to pay dividends on our common stock and, consequently, our stockholders' ability to achieve a return on their investment will depend on appreciation of the value of our common stock.

We have never declared or paid cash dividends on our common stock. We currently intend to retain all available funds and any future earnings to support operations and to finance the growth and development of our business. We do not intend to declare or pay any cash dividends on our capital stock in the foreseeable future. As a result, any investment return on our common stock will depend upon increases in the value for our common stock, which is not certain.

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

Our amended and restated certificate of incorporation and our amended and restated bylaws each contain provisions that could depress the market price of our common stock by acting to discourage, delay, or prevent a change in control of our company or changes in our management that the stockholders of our company may deem advantageous. These provisions, among other things:

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

As a Delaware corporation, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which prohibits a Delaware corporation from engaging in a business combination specified in the statute with an interested stockholder (as defined in the statute) for a period of three years after the date of the transaction in which the person first becomes an interested stockholder, unless the business combination is approved in advance by a majority of the independent directors or by the holders of at least two-thirds of the outstanding disinterested shares. The application of Section 203 of the Delaware General Corporation Law could also have the effect of delaying or preventing a change of control of our company.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the sole and exclusive forum, to the fullest extent permitted by law, for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a breach of a fiduciary duty owed by any director, officer or other employee to us or our stockholders, (3) any action asserting a claim against us or any director, officer, or other employee arising pursuant to the Delaware General Corporation Law, (4) any action to interpret, apply, enforce, or determine the validity of our second amended and restated certificate of incorporation or amended and restated bylaws, or (5) any other action asserting a claim that is governed by the internal affairs doctrine, shall be the Court of Chancery of the State of Delaware (or another state court or the federal court located within the State of Delaware if the Court of Chancery does not have or declines to accept jurisdiction), in all cases subject to the court's having jurisdiction over indispensable parties named as defendants. In addition, our amended and restated certificate of incorporation will provide that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act but that the forum selection provision will not apply to claims brought to enforce a duty or liability created by the Exchange Act. Although we believe these provisions benefit us by providing increased consistency in the application of Delaware law for the specified types of actions and proceedings, the provisions may have the effect of discouraging lawsuits against us or our directors and officers. Alternatively, if a court were to find the choice of forum provision contained in our second 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 harm our business, financial condition, and operating results. For example, under the Securities Act, federal courts have concurrent jurisdiction over all suits brought to enforce any duty or liability created by the Securities Act, and investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Any

person or entity purchasing or otherwise acquiring any interest in our shares of capital stock shall be deemed to have notice of and consented to this exclusive forum provision, but will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

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

As of December 31, 2019, we had U.S. federal and state net operating loss, or NOL, carryforwards of $14.0 million and $0.2 million, respectively, which may be available to offset future taxable income. As of December 31, 2019, we also had federal tax credits of $2.3 million, which may be used to offset future tax liabilities. These NOLs and tax credit carryforwards will begin to expire in 2036.

Use of our NOL carryforwards and tax credit carryforwards depends on many factors, including having current or future taxable income, which cannot be assured. Our U.S. NOL and tax credit carryforwards could expire unused and be unavailable to offset future taxable income or income tax liabilities because of their limited duration or because of restrictions under U.S. tax law. In addition, for taxable years beginning after December 31, 2020, the deductibility of federal NOLs generated in taxable years beginning after December 31, 2017 is limited to 80% of our taxable income in such year (after taking into account utilization of NOLs generated in taxable years beginning before January 1, 2018), where taxable income is determined without regard to such NOL deduction itself. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, and certain corresponding provisions of state law, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change NOL and tax credit carryforwards to offset future taxable income or taxes. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders (or groups of stockholders), each of whom owns at least 5% of a corporation's stock, increases by more than 50 percentage points over its lowest ownership percentage within a specified testing period. We believe we have experienced ownership changes in the past, and we believe it is likely that we will experience an additional ownership change in the future as a result of subsequent shifts in our stock ownership, some of which are outside our control. If finalized, Treasury Regulations currently proposed under Section 382 of the Code may further limit our ability to utilize our pre-change NOL and tax credit carryforwards if we undergo additional ownership changes as a result of our initial public offering.

If we earn taxable income in the future, we expect that our ability to use existing NOL and tax credit carryforwards to offset such taxable income will be materially limited as a result of these ownership changes. The application of such limitations may cause U.S. federal income taxes (and possibly state income taxes) to be paid by us earlier than they otherwise would be paid if such limitations were not in effect and could cause such NOLs and tax credit carryforwards to expire unused, in each case reducing or eliminating the benefit of such NOLs and tax credit carryfowards.

To the extent we are not able to offset our future taxable income with our NOLs or offset future taxes with our tax credit carryforwards, this would adversely affect our operating results and cash flows. These same risks can arise in the context of state income and franchise tax given many states conform to federal law and rely on federal authority for determining state NOLs.

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

Use of Proceeds from IPO of Common Stock

On October 14, 2020, we completed our IPO pursuant to which we issued and sold an aggregate of 13,664,704 shares of our common stock at the IPO price of $17.00 per share.

The offer and sale of all of the shares of our common stock in the IPO were registered under the Securities Act pursuant to our Registration Statement on Form S-1, as amended (File No. 333-248918), which was declared effective on October 8, 2020. Citigroup, Cowen, and Evercore ISI acted as joint book-running managers for the IPO. Needham & Company acted as lead manager for the IPO.

We received gross proceeds from our IPO of approximately $232.3 million, and net proceeds of $213.5 million after deducting $16.3 million in underwriting discounts and commissions and $2.5 million of other offering expenses. None of the underwriting discounts and commissions or other offering expenses were incurred or paid, directly or indirectly, to any of our directors or officers or their associates or to persons owning 10% or more of our common stock or to any of our affiliates.

The net proceeds from the IPO have been used and will be used, to advance SL-172154 through the completion of our ongoing and planned Phase 1 clinical trials and to commence a Phase 2 clinical program, to advance SL-279252 through the completion of our ongoing Phase 1 clinical trial, to develop and advance additional product candidates derived from our platforms through IND-enabling studies and to commence Phase 1 clinical trials, and for working capital and general corporate purposes. There has been no material change in our intended use of proceeds from our IPO as described in our final prospectus filed with the SEC pursuant to Rule 424(b)(4) on October 13, 2020.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

None.

Item 6. Exhibits

The exhibits filed or furnished as part of this Quarterly Report on Form 10-Q are set forth below.

Exhibit Number	Description of Exhibit
3.1	Amended and Restated Certificate of Incorporation of Shattuck Labs, Inc. (incorporated by reference from Exhibit 3.1 to Shattuck's Current Report on Form 8-K filed on October 14, 2020 (Commission File No. 001-39593))
3.2	Amended and Restated Bylaws of Shattuck Labs, Inc. (incorporated by reference from Exhibit 3.2 to Shattuck's Current Report on Form 8-K filed on October 14, 2020 (Commission File No. 001-39593)
4.1	Form of common stock certificate of Shattuck (incorporated by reference from Exhibit 4.1 of Shattuck's Amendment No. 2 to Registration Statement on Form S-1 filed on October 8, 2020 (Commission File No. 333-248918))
4.2	Second Amended and Restated Investors' Rights Agreement, dated as of June 12, 2020, by and among Shattuck Labs, Inc. and certain of its stockholders (incorporated by reference from Exhibit 4.2 of Shattuck's Amendment No. 2 to Registration Statement on Form S-1 filed on October 8, 2020 (Commission File No. 333-248918))
10.1	2020 Equity Incentive Plan (incorporated by reference from Exhibit 10.9 of Shattuck's Amendment No. 2 to Registration Statement on Form S-1 filed on October 8, 2020 (Commission File No. 333-248918))
10.2	2020 Employee Stock Purchase Plan (incorporated by reference from Exhibit 10.10 of Shattuck's Amendment No. 2 to Registration Statement on Form S-1 filed on October 8, 2020 (Commission File No. 333-248918))
31.1*	Certification of the principal executive officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934.
31.2*	Certification of the principal financial officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934.
32.1* (1)	Certification of the principal executive officer and principal financial officer pursuant to 18 U.S.C. Section 1350 and Rule 13a-14(b) under the Securities Exchange Act of 1934
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document
104*	The cover page from the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, formatted in Inline XBRL (included in Exhibit 101).

* Filed herewith

(1) The certifications on Exhibit 32 hereto are deemed not "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that Section. Such certifications will not be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

SIGNATURES

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

Shattuck Labs, Inc.

Date: November 13, 2020

By: /s/ Dr. Taylor Schreiber

Dr. Taylor Schreiber
Chief Executive Officer
(principal executive officer)

Date: November 13, 2020

By: /s/ Andrew R. Neill

Andrew R. Neill
Vice President of Finance, Corporate Strategy
(principal financial and accounting officer)

Exhibit 31.1

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

I, Taylor Schreiber, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Shattuck Labs, Inc.;

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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 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 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: November 13, 2020

By: /s/ Dr. Taylor Schreiber

Dr. Taylor Schreiber
Chief Executive Officer
(principal executive officer)

Exhibit 31.2

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

I, Andrew R. Neill, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Shattuck Labs, Inc.;

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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 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 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: November 13, 2020

By: /s/ Andrew R. Neill

Andrew R. Neill
Vice President of Finance, Corporate Strategy
(principal financial and accounting 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 Shattuck Labs, Inc. (the "Company") for the period ended September 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(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: November 13, 2020

By: /s/ Dr. Taylor Schreiber
Dr. Taylor Schreiber
Chief Executive Officer
(principal executive officer)

Date: November 13, 2020

By: /s/ Andrew R. Neill
Andrew R. Neill
Vice President of Finance, Corporate Strategy
(principal financial and accounting officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. §1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Note: A signed original of this written statement required by §906 has been provided to Shattuck Labs, Inc. and will be retained by Shattuck Labs, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.