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

FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED March 31, 2021
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 001-38501

SCHOLAR ROCK HOLDING CORPORATION
(Exact name of registrant as specified in its charter)

Delaware	82-3750435
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
301 Binney Street, 3rd Floor Cambridge, Massachusetts	02142
(Address of principal executive offices)	**(Zip Code)**

(857) 259 3860
(Registrant's telephone number, including area code)

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 $0.001 per share	SRRK	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, a 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 ☒
The number of outstanding shares of the Registrant's Common Stock as of May 10, 2021 was 34,415,327.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q ("Quarterly Report"), including the documents incorporated by reference, contains forward-looking statements within the meaning of the federal securities laws, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. We intend these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995 and are including this statement for purposes of complying with those safe harbor provisions. All statements other than statements of historical facts contained in this Quarterly Report are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "may", "will", "should", "expects", "intends", "plans", "anticipates", "believes", "estimates", "predicts", "potential", "continue" or the negative of these terms or other comparable terminology. Some of the risks and uncertainties that may cause our actual results, performance or achievements to differ materially from those expressed or implied by forward-looking statements include, among others, the following:

- the success, cost and timing of clinical trials for apitegromab (SRK-015), including the results, progress and completion of clinical trials, and the results, and the timing of results, from these trials;
- the success, cost and timing of clinical trials for SRK-181, including the results, progress and completion of our DRAGON Phase 1 clinical trial for SRK-181 and any future clinical trials for SRK-181, and the results, and the timing of results, from these trials;
- the success, cost and timing of our other product development activities, preclinical studies and clinical trials, and the results, and timing of results, from these studies and trials;
- our success in identifying and executing a development program for additional indications for apitegromab, SRK-181 and in identifying product candidates from our other programs;
- the clinical utility of our product candidates and their potential advantages over other therapeutic options;
- our ability to obtain, generally or on terms acceptable to us, funding for our operations, including funding necessary to complete further development and, upon successful development, if approved, commercialization of apitegromab, SRK-181 or any of our future product candidates;
- risks associated with the COVID-19 pandemic, which may adversely impact our business, preclinical studies, clinical trials and financial results;
- the potential for our identified research priorities to advance our proprietary platform, development programs or product candidates;
- the timing, scope, or likelihood of our ability to obtain and maintain regulatory approval from the U.S. Food and Drug Administration ("FDA"), the European Commission ("EC") and other regulatory authorities for apitegromab, SRK-181 and any future product candidates, and any related restrictions, limitations or warnings in the label of any approved product candidate;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates and the duration of such protection;
- our ability and the potential to successfully manufacture our product candidates for clinical trials and for commercial use, if approved;
- our ability to establish or maintain collaborations or strategic relationships, including our collaboration with Gilead Sciences, Inc. ("Gilead");
- our expectations relating to the potential of our proprietary platform technology;

- our ability to obtain additional funding when necessary;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets, either alone or in combination with others;
- our expectations related to the use of our cash reserves;
- the impact of new laws and regulations or amendments to existing laws and regulations;
- developments and projections relating to our competitors and our industry;
- our estimates and expectations regarding cash and expense levels, future revenue, capital requirements and needs for additional financing, including our expected use of proceeds from our public offerings, and liquidity sources;
- our expectations regarding the period during which we qualify as an emerging growth company ("EGC") under the Jumpstart Our Business Startups Act; and
- other risks and uncertainties, including those listed under the caption Part II, Item 1A "Risk Factors".

The risks set forth above are not exhaustive. Other sections of this report may include additional factors that could adversely affect our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time and it is not possible for management to predict all risk factors, nor can we assess the impact of all risk factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Given these risks and uncertainties, investors should not place undue reliance on forward-looking statements as a prediction of actual results. Investors should also refer to our most recent Annual Report on Form 10-K and our Quarterly Reports on Form 10-Q for future periods and Current Reports on Form 8-K as we file them with the SEC, and to other materials we may furnish to the public from time to time through Current Reports on Form 8-K or otherwise, for a discussion of risks and uncertainties that may cause actual results, performance or achievements to differ materially from those expressed or implied by forward-looking statements. We expressly disclaim any responsibility to update any forward-looking statements to reflect changes in underlying assumptions or factors, new information, future events, or otherwise, and you should not rely upon these forward-looking statements after the date of this report.

We may from time to time provide estimates, projections and other information concerning our industry, the general business environment, and the markets for certain diseases, including estimates regarding the potential size of those markets and the estimated incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties, and actual events, circumstances or numbers, including actual disease prevalence rates and market size, may differ materially from the information reflected in this Quarterly Report. Unless otherwise expressly stated, we obtained this industry, business information, market data, prevalence information and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data, and similar sources, in some cases applying our own assumptions and analysis that may, in the future, prove not to have been accurate.

SCHOLAR ROCK HOLDING CORPORATION
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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

SCHOLAR ROCK HOLDING CORPORATION
CONSOLIDATED BALANCE SHEETS
(Unaudited)
(In thousands, except share and per share data)

	March 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 159,108	$ 160,358
Marketable securities	155,581	180,673
Prepaid expenses and other current assets	3,803	3,373
Total current assets	318,492	344,404
Property and equipment, net	8,925	8,121
Operating lease right-of-use asset	29,675	32,261
Restricted cash	2,498	2,498
Other long-term assets	996	1,021
Total assets	$ 360,586	$ 388,305
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,196	$ 3,409
Accrued expenses	14,553	14,958
Operating lease liability	5,670	5,366
Deferred revenue	47,301	18,816
Other current liabilities	235	15
Total current liabilities	69,955	42,564
Long-term portion of operating lease liability	25,324	27,093
Long-term debt	24,763	24,680
Other long-term liabilities	4	5
Long-term portion of deferred revenue	—	33,193
Total liabilities	120,046	127,535
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at March 31, 2021 and December 31, 2020; no shares issued and outstanding at March 31, 2021 and December 31, 2020	—	—
Common stock, $0.001 par value; 150,000,000 shares authorized; 34,398,390 and 34,152,470 shares issued and outstanding as of March 31, 2021 and December 31, 2020, respectively	34	34
Additional paid-in capital	512,485	505,069
Accumulated other comprehensive income (loss)	23	(2)
Accumulated deficit	(272,002)	(244,331)
Total stockholders' equity	240,540	260,770
Total liabilities and stockholders' equity	$ 360,586	$ 388,305

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

SCHOLAR ROCK HOLDING CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)
(In thousands, except share and per share data)

	Three Months Ended March 31,	
	2021	2020
Revenue	$ 4,708	$ 5,030
Operating expenses:		
Research and development	22,549	16,902
General and administrative	9,366	5,822
Total operating expenses	31,915	22,724
Loss from operations	(27,207)	(17,694)
Other income (expense), net	(464)	624
Net loss	$ (27,671)	$ (17,070)
Net loss per share, basic and diluted	$ (0.76)	$ (0.58)
Weighted average common shares outstanding, basic and diluted	36,380,438	29,527,349
Comprehensive loss:		
Net loss	$ (27,671)	$ (17,070)
Other comprehensive income:		
Unrealized gain on marketable securities	25	197
Total other comprehensive income	25	197
Comprehensive loss	$ (27,646)	$ (16,873)

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

SCHOLAR ROCK HOLDING CORPORATION
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(Unaudited)
(In thousands, except share and per share data)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2020	**34,152,470**	**$ 34**	**$ 505,069**	**$ (2)**	**$ (244,331)**	**$ 260,770**
Unrealized gain on marketable securities	—	—	—	25	—	25
Exercise of stock options	245,920	—	2,743	—	—	2,743
Equity-based compensation expense	—	—	4,673	—	—	4,673
Net Loss	—	—	—	—	(27,671)	(27,671)
Balance at March 31, 2021	**34,398,390**	**$ 34**	**$ 512,485**	**$ 23**	**$ (272,002)**	**$ 240,540**

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2019	**29,792,922**	**$ 30**	**$ 270,682**	**$ 37**	**$ (157,848)**	**$ 112,901**
Unrealized gain on marketable securities	—	—	—	197	—	197
Exercise of stock options	40,252	—	405	—	—	405
Equity-based compensation expense	—	—	2,214	—	—	2,214
Net loss	—	—	—	—	(17,070)	(17,070)
Balance at March 31, 2020	**29,833,174**	**$ 30**	**$ 273,301**	**$ 234**	**$ (174,918)**	**$ 98,647**

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

SCHOLAR ROCK HOLDING CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(In thousands)

	Three Months Ended March 31,	
	2021	2020
Cash flows from operating activities:		
Net loss	$ (27,671)	$ (17,070)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	590	391
Amortization of debt discount and debt issuance costs	83	—
Loss on disposal of property and equipment	24	—
Equity-based compensation	4,673	2,214
Amortization/accretion of investment securities	248	(177)
Non-cash operating lease expense	1,537	259
Change in operating assets and liabilities:		
Accounts receivable	—	25,000
Prepaid expenses and other current assets	619	(806)
Other assets	25	(732)
Accounts payable	(1,228)	1,089
Accrued expenses	506	(2,234)
Operating lease liabilities	(1,465)	(268)
Deferred revenue	(4,708)	(5,030)
Other liabilities	223	—
Net cash (used in) provided by operating activities	(26,544)	2,636
Cash flows from investing activities:		
Purchases of property and equipment	(2,312)	(209)
Purchases of marketable securities	(30,131)	(19,400)
Maturities of marketable securities	55,000	75,700
Net cash provided by investing activities	22,557	56,091
Cash flows from financing activities:		
Proceeds from stock option exercises	2,743	405
Other	(6)	(6)
Net cash provided by financing activities	2,737	399
Net (decrease) increase in cash, cash equivalents and restricted cash	(1,250)	59,126
Cash, cash equivalents and restricted cash, beginning of period	162,856	38,806
Cash, cash equivalents and restricted cash, end of period	$ 161,606	$ 97,932
Supplemental disclosure of non-cash items:		
Property and equipment purchases in accounts payable and accrued expenses	$ 473	$ 10
Supplemental cash flow information:		
Cash paid for interest	$ 491	$ —

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

SCHOLAR ROCK HOLDING CORPORATION
Notes to Consolidated Financial Statements
(Unaudited)

1. Nature of the Business

Scholar Rock Holding Corporation and its subsidiaries (collectively, the "Company") is a biopharmaceutical company focused on the discovery and development of innovative medicines for the treatment of serious diseases in which signaling by protein growth factors plays a fundamental role. The Company's novel understanding of the molecular mechanisms of growth factor activation enabled the development of a proprietary platform for the discovery and development of monoclonal antibodies that locally and selectively target these signaling proteins at the cellular level. The Company's first product candidate, apitegromab (formerly SRK-015), is a selective, fully human, monoclonal antibody, with a unique mechanism of action that results in the inhibition of the activation of the growth factor, myostatin, in skeletal muscle. Apitegromab is being developed as a potential first muscle-directed therapy for the treatment of spinal muscular atrophy ("SMA"). Apitegromab was evaluated in the Company's TOPAZ Phase 2 proof-of-concept trial for the treatment of patients with Type 2 and Type 3 SMA and positive 12-month top-line results were announced in April 2021 demonstrating apitegromab's transformative potential. A Phase 3 trial in patients with non-ambulatory Type 2 and 3 SMA is anticipated to initiate by year-end 2021. The Company's second product candidate, SRK-181, is being developed for the treatment of cancers that are resistant to checkpoint inhibitor ("CPI") therapies, such as anti-PD-1 or anti-PD-L1 antibody therapies. SRK-181 is a selective inhibitor of the activation of latent transforming growth factor beta-1 ("TGFβ1") that is being investigated in the DRAGON Phase 1 proof-of-concept trial in patients with locally advanced or metastatic solid tumors that exhibit primary resistance to anti-PD-(L)1 antibodies. The Company is progressing the Part A dose escalation portion of the DRAGON trial and plans to advance to Part B dose expansion in mid-2021. Additionally, the Company continues to create a pipeline of novel product candidates with the potential to transform the lives of patients suffering from a wide range of serious diseases, including neuromuscular disorders, cancer, and fibrosis. The Company was originally formed in May 2012. Its principal offices are in Cambridge, Massachusetts.

Since its inception, the Company's operations have focused on research and development of monoclonal antibodies that selectively inhibit activation of growth factors for therapeutic effect, as well as establishing the Company's intellectual property portfolio and performing research and development activities. The Company has primarily financed its operations through various equity financings, including the initial public offering of its common stock (the "IPO") in May 2018, a secondary offering of common stock in June 2019, and a follow-on offering of common stock and pre-funded warrants completed in November 2020, as well as research and development collaboration agreements.

Revenue generation activities have been limited to two collaborations, both containing research services and the issuance of a license. The first agreement, executed in 2013, was with Janssen Biotech, Inc. ("Janssen"), a subsidiary of Johnson & Johnson. The second agreement (the "Gilead Collaboration Agreement"), executed in December 2018, was with Gilead Sciences, Inc. ("Gilead"). The Company began recognizing revenue on the Gilead Collaboration Agreement in 2019. No revenues have been recorded from the sale of any commercial product.

The Company is subject to a number of risks similar to other life science companies, including, but not limited to, successful discovery and development of its drug candidates, raising additional capital, development by its competitors of new technological innovations, protection of proprietary technology and regulatory approval and market acceptance of the Company's product candidates. The Company anticipates that it will continue to incur significant operating losses for the next several years as it continues to develop its product candidates. The Company believes that its existing cash, cash equivalents and marketable securities at March 31, 2021 will be sufficient to allow the Company to fund its current operations through at least a period of one year after the date the financial statements are issued.

2. Summary of Significant Accounting Policies

Summary of Significant Accounting Policies

The significant accounting policies used in preparation of the unaudited consolidated financial statements are described in the Company's audited consolidated financial statements as of and for the year ended December 31, 2020, and the

notes thereto, which are included in the Company's Annual Report on Form 10-K. There have been no material changes to the significant accounting policies previously disclosed in the Company's Annual Report on Form 10-K for the year ended December 31, 2020.

Cash, Cash Equivalents and Restricted Cash

The following table reconciles cash, cash equivalents and restricted cash per the balance sheet to the statement of cash flows (in thousands):

	As of March 31,	
	2021	2020
Cash and cash equivalents	$ 159,108	$ 95,434
Restricted cash	2,498	2,498
	$ 161,606	$ 97,932

Unaudited Interim Financial Information

The consolidated financial statements of the Company included herein have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC"). The unaudited consolidated financial statements include the accounts of Scholar Rock Holding Corporation and its wholly owned subsidiaries. All intercompany transactions and balances have been eliminated in consolidation. In the opinion of management, the information furnished reflects all adjustments, all of which are of a normal and recurring nature, necessary for a fair presentation of the results for the reported interim periods. The Company considers events or transactions that occur after the balance sheet date but before the financial statements are issued to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure. The results of operations for interim periods are not necessarily indicative of results to be expected for the full year or any other interim period.

Use of Estimates

The preparation of financial statements in accordance with GAAP requires management to make estimates and judgments that may affect the reported amounts of assets and liabilities and related disclosures of contingent assets and liabilities at the date of the financial statements and the related reporting of revenues and expenses during the reporting period. Management bases its estimates on historical experience and on various assumptions that are believed to be reasonable under the circumstances. Actual results could differ from those estimates.

Recently Issued Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. The standard requires that a financial asset or a group of financial assets measured at amortized cost basis to be presented at the net amount expected to be collected. Under current GAAP, a company only considered past events and current conditions in measuring an incurred loss. Under ASU 2016-13, the information that a company must consider is broadened in developing an expected credit loss estimate for assets measured either collectively or individually. The use of forecasted information incorporates more timely information in the estimate of expected credit loss. The guidance is applied using a modified retrospective, or prospective approach, depending on a specific amendment. In November 2019, the FASB deferred the effective date for smaller reporting companies to fiscal years beginning after December 15, 2022. The Company does not anticipate a material impact to its net financial position or disclosures as a result of the adoption of ASU 2016-13.

3. Fair Value of Financial Assets and Liabilities

The following tables summarize the assets and liabilities measured at fair value on a recurring basis at March 31, 2021 and December 31, 2020 (in thousands):

	Fair Value Measurements at March 31, 2021			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds, included in cash and cash equivalents	$ 144,887	$ 144,887	$ —	$ —
U.S. Treasury obligations, included in cash and cash equivalents	—	—	—	—
Marketable securities:				
U.S. Treasury obligations	155,581	155,581	—	—
Total assets	$ 300,468	$ 300,468	$ —	$ —

	Fair Value Measurements at December 31, 2020			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds, included in cash and cash equivalents	$ 119,841	$ 119,841	$ —	$ —
U.S. Treasury obligations, included in cash and cash equivalents	9,998	9,998	—	—
Marketable securities:				
U.S. Treasury obligations	180,673	180,673	—	—
Total assets	$ 310,512	$ 310,512	$ —	$ —

Cash, cash equivalents and marketable securities are Level 1 assets and include investments in money market funds and U.S. government securities that are valued using quoted market prices. Accordingly, money market funds and government funds are categorized as Level 1 as of March 31, 2021 and December 31, 2020. There were no transfers of assets between fair value measurement levels during the three months ended March 31, 2021 or 2020.

The carrying amounts reflected in the balance sheets for prepaid expenses and other current assets, accounts payable, and accrued expenses approximate their fair values at March 31, 2021 and December 31, 2020, due to their short-term nature.

The Company believes the terms of its debt reflect current market conditions for an instrument with similar terms and maturity, therefore the carrying value of the Company's debt approximates its fair value based on Level 3 of the fair value hierarchy.

4. Marketable Securities

The following table summarizes the Company’s investments as of March 31, 2021 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Marketable securities available-for-sale:				
U.S. Treasury obligations	$ 155,558	$ 23	$ —	$ 155,581
Total available-for-sale securities	$ 155,558	$ 23	$ —	$ 155,581

The following table summarizes the Company’s investments as of December 31, 2020 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Marketable securities available-for-sale:				
U.S. Treasury obligations	$ 180,675	$ 7	$ (9)	$ 180,673
Total available-for-sale securities	$ 180,675	$ 7	$ (9)	$ 180,673

5. Accrued Expenses

As of March 31, 2021 and December 31, 2020, accrued expenses consist of the following (in thousands):

	As of	
	March 31, 2021	December 31, 2020
Accrued external research and development expense	$ 8,327	$ 5,387
Accrued payroll and related expenses	3,269	6,663
Accrued professional and consulting expense	1,858	1,141
Accrued other	820	476
Accrued payable for property and equipment	279	1,291
	$ 14,553	$ 14,958

6. Equity-Based Compensation

The Company recorded equity-based compensation expense related to all equity-based awards, which was allocated as follows in the consolidated statements of operations and comprehensive loss for the three months ended March 31, 2021 and 2020 (in thousands):

	Three Months Ended March 31,	
	2021	2020
Research and development expense	$ 2,110	$ 815
General and administrative expense	2,563	1,399
	$ 4,673	$ 2,214

The following table summarizes the Company's unrecognized equity-based compensation expense as of March 31, 2021:

	As of March 31, 2021	
	Unrecognized expense (in thousands)	Period of recognition (years)
Restricted Stock Awards	$ 150	0.4
Restricted Stock Units	14,223	3.8
Stock Options	60,498	2.8
	$ 74,871	

Restricted Stock Awards

The following table summarizes the Company's restricted stock award activity for the current year:

	Number of Shares	Weighted Average Fair Value per Share at Issuance
Restricted stock awards as of December 31, 2020	57,969	$ 5.77
Vested	(24,283)	$ 5.77
Restricted stock awards as of March 31, 2021	33,686	$ 5.77

Restricted Stock Units

The following table summarizes the Company's restricted stock unit activity for the current year:

	Number of Units	Weighted Average Grant Date Fair Value
Restricted stock units as of December 31, 2020	—	$ —
Granted	259,007	$ 59.80
Forfeited	(11,940)	$ 59.16
Restricted stock units as of March 31, 2021	247,067	$ 59.83

Stock Options

The following table summarizes the Company's stock option activity for the current year:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2020	3,679,931	$ 14.96	8.01	$ 123,600
Granted	970,639	$ 59.38		
Exercised	(245,920)	$ 11.15		
Cancelled	(120,657)	$ 28.25		
Outstanding as of March 31, 2021	4,283,993	$ 24.87	8.29	$ 118,628
Options exercisable as of March 31, 2021	870,143	$ 14.42	7.64	$ 31,532

Using the Black-Scholes option pricing model, the weighted average fair value of options granted during the three months ended March 31, 2021 was $43.54.

The following weighted average assumptions were used in determining the fair value of options granted in the three months ended March 31, 2021 and 2020:

	Three Months Ended March 31,	
	2021	2020
Risk-free interest rate	0.70 %	1.42 %
Expected dividend yield	0.0 %	0.0 %
Expected term (years to liquidity)	6.24	6.25
Expected volatility	87.82 %	81.65 %

7. Commitments and Contingencies

Operating Leases

620 Memorial Facility Lease

In March 2015, the Company entered into a 5-year lease of office and laboratory space for its corporate headquarters (the "Lease") at 620 Memorial Drive in Cambridge, Massachusetts. The Lease was amended in February 2018, to add an additional space (the "Expansion Space") at the current location and to extend the Lease term (the "Amended Lease"). The Amended Lease covers approximately 20,751 square feet and expires in September 2023. Annual rent payments, including the Expansion Space, increase from $1.4 million to $1.7 million over the term of the Amended Lease. Variable lease payments include the Company's allocated share of costs incurred and expenditures made by the landlord in the operation and management of the building. The Company has the option to extend the term of the Amended Lease for one additional term of 5 years commencing after the Amended Lease expires.

On October 5, 2020, the Company entered into a Sublease Agreement (the "Sublease") with Orna Therapeutics, Inc. (the "Subtenant") to sublease the space covered by the Amended Lease at 620 Memorial Drive, Cambridge, Massachusetts. The Sublease term commenced on February 1, 2021 and ends on August 31, 2023, unless terminated earlier. The Sublease provides for initial annual base rent of approximately $1.9 million. The Subtenant is obligated to pay for certain costs, taxes and operating expenses, subject to certain exclusions. The Sublease is subordinate to that certain Indenture of Lease, dated March 5, 2015, by and between 620 Memorial Leasehold LLC and Scholar Rock, Inc., as amended.

301 Binney Facility Lease

In November 2019, the Company entered into a lease of office and laboratory space at 301 Binney Street in Cambridge, Massachusetts to be used as its new corporate headquarters. The expiration date of the lease is in August 2025 and the Company has the option to extend the term by two years. The base rent is $6.9 million per year, subject to an annual increase of 3.5%, and the Company was subject to a free-rent period through mid-August 2020. Variable lease payments include the Company's allocated share of costs incurred and expenditures made by the landlord in the operation and management of the building. Under this lease, the Company will receive lease incentives of $14.1 million in the form of an allowance for tenant improvements related to the design and build out of the space, of which the Company has received $11.9 million as of March 31, 2021. In connection with the lease, the Company has secured a letter of credit for $2.3 million which renews automatically each year. The lease commencement date, for accounting purposes, was reached in September 2020.

Other information related to the Company's leases (excluding the Company's sublease income of $0.3 million for the three months ended March 31, 2021) is as follows (in thousands, except lease term and discount rate):

	For Three Months Ended March 31, 2021
Lease Cost:	
Operating lease cost	$ 2,154
Variable lease cost	608
Total lease cost	$ 2,762

	For Three Months Ended March 31, 2021
Other information:	
Operating cash flows used for operating leases [1]	$ 3,317
Weighted average remaining lease term	4.2 years
Weighted average incremental borrowing rate	7.5 %

[1] Operating cash flows used for operating leases are presented net of certain tenant improvement reimbursements received related to the construction of the Company's office and laboratory space at 301 Binney Street.

Specifica Antibody Library

On December 20, 2019 (the "Effective Date"), the Company entered into a Library Development and Transfer Agreement with Specifica Inc. ("Specifica"), whereby Specifica is responsible for developing and delivering a customized antibody display library (the "Library") for the Company to use to identify antibodies for further research, development, and commercialization. As of March 31, 2021 the Company has paid $1.2 million of the total $3.7 million in fees expected to be paid through 2023 related to the Library.

Legal Proceedings

The Company, from time to time, may be party to litigation arising in the ordinary course of its business. The Company was not subject to any material legal proceedings during the three months ended March 31, 2021 and 2020.

8. Debt

On October 16, 2020 (the "Closing Date") the Company entered into a Loan and Security Agreement with Oxford Finance LLC and Silicon Valley Bank for $50.0 million (the "Loan and Security Agreement"). The first tranche of $25.0 million was funded on the Closing Date. The second $25.0 million tranche is available through December 31, 2021 upon dosing of the first patient in a Phase 3 trial for apitegromab and dosing of the first patient in Part B of the DRAGON Phase 1 trial for SRK-181. The Loan and Security Agreement will mature on May 1, 2025 and requires interest only payments for the first two years. The interest rate on the unpaid principal will be the greater of the Wall Street Journal prime rate plus 4.60% or 7.85% per annum. Prepayment is permitted and may include either a 2% or 3% fee (of the principal amount being prepaid), depending on when the prepayment is made. The Company is also required to make a final payment equal to 4% of the original principal amount.

9. Agreements

Collaboration with Gilead

On December 19, 2018 (the "Effective Date"), the Company entered into a Master Collaboration Agreement (the "Gilead Collaboration Agreement") with Gilead to discover and develop specific inhibitors of transforming growth factor beta ("TGFβ") activation focused on the treatment of fibrotic diseases. Under the collaboration, Gilead has exclusive options to license worldwide rights to product candidates that emerge from three of the Company's TGFβ programs (each a "Gilead Program"). Pursuant to the Gilead Collaboration Agreement, the Company is responsible for antibody discovery and preclinical research through product candidate nomination, after which, upon exercising the option for a Gilead Program, Gilead will be responsible for the program's preclinical and clinical development and commercialization. Such option may be exercised by Gilead at any time from the Effective Date through a date that is 90 days following the expiration of the Research Collaboration Term for a given Gilead Program, or until termination of the Gilead Program, whichever is earlier (the "Option Exercise Period").

Prior to Gilead's exercise of an option, the Company has the lead responsibility for drug discovery and pre-clinical development of all Gilead Programs through to Development Candidate Nomination. Within a certain period of time after receiving a data package for a Development Candidate Nomination, Gilead may exercise its option to enter into a

Form of License Agreement for exclusive rights to develop, manufacture and commercialize the licensed antibodies and licensed products of such Gilead Program.

Revenue associated with the research and development and license performance obligations relating to the Gilead Programs is recognized as revenue as the research and development services are provided using an input method, according to the costs incurred on each Gilead Program and the costs expected to be incurred in the future to satisfy the performance obligation. The transfer of control occurs over time. In management's judgment, this input method is the best measure of progress towards satisfying the performance obligation. The amounts allocated to the three material rights will be recognized when Gilead exercises each respective option and delivers the underlying license and transfer of know-how, or immediately as each option expires unexercised. The amounts received that have not yet been recognized as revenue are recorded in deferred revenue on the Company's consolidated balance sheet.

None of the performance obligations have been fully satisfied as of March 31, 2021. A $25.0 million preclinical milestone was achieved in December 2019 for the successful demonstration of efficacy in preclinical in vivo proof-of-concept studies. As a result, the associated $25.0 million was included in the consideration transferred and proportionally allocated to the performance obligations, as it was probable that a future material reversal will not occur.

In the three months ended March 31, 2021, the Company recognized $4.7 million in revenue in the Company's consolidated statements of operations and comprehensive loss under the Gilead Collaboration Agreement. The aggregate amount of the transaction price allocated to the Company's unsatisfied performance obligations and recorded in deferred revenue at March 31, 2021 is $47.3 million. The Company will recognize the $14.1 million of deferred revenue related to the research and development services based on a cost input method, over the remaining research term for each respective Gilead Program, which is a maximum of nine months as of March 31, 2021; each research term is dependent on the timing of Gilead either exercising its options for the Gilead Programs or terminating further development on the Gilead Programs prior to the expiration date of the research term. The $33.2 million of deferred revenue related to the material rights will be recognized as options are exercised by Gilead or at the conclusion of the Option Exercise Period.

10. Net Loss per Share

The Company calculates basic net loss per share by dividing net loss by the weighted average number of common shares outstanding, excluding restricted common stock. The weighted average number of common shares used in the basic and diluted net loss per share calculation include the pre-funded warrants issued in connection with the Company's November 2, 2020 follow-on offering as the warrants are exercisable at any time for nominal cash consideration. As of March 31, 2021 no pre-funded warrants have been exercised and 2,179,487 pre-funded warrants are outstanding. The Company has generated a net loss in all periods presented, so the basic and diluted net loss per share are the same, as the inclusion of the potentially dilutive securities would be anti-dilutive.

The following table sets forth the outstanding common stock equivalents, presented based on amounts outstanding at each period end, that have been excluded from the calculation of diluted net loss per share for the periods indicated because their inclusion would have been anti-dilutive:

	Three Months Ended March 31,	
	2021	2020
Restricted stock awards	33,686	227,064
Restricted stock units	247,067	—
Warrant	—	7,614
Stock options	4,283,993	3,510,965
	4,564,746	3,745,643

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q (the "Quarterly Report"), and the audited financial information and the notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2020.

Our actual results and timing of certain events may differ materially from the results discussed, projected, anticipated, or indicated in any forward-looking statements. We caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Quarterly Report. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this Quarterly Report, they may not be predictive of results or developments in future periods.

The following information and any forward-looking statements should be considered in light of factors discussed elsewhere in this Quarterly Report, including those risks identified under Part II, Item 1A. Risk Factors.

We caution readers not to place undue reliance upon any such forward-looking statements, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the SEC, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

Overview

We are a biopharmaceutical company focused on the discovery and development of innovative medicines for the treatment of serious diseases in which signaling by protein growth factors plays a fundamental role. Our novel understanding of the molecular mechanisms of growth factor activation enabled us to develop a proprietary platform for the discovery and development of monoclonal antibodies that locally and selectively target the precursor, or latent, forms of growth factors. By targeting the signaling proteins at the cellular level and acting in the disease microenvironment, we believe we may avoid the historical dose-limiting safety challenges associated with inhibiting growth factors for therapeutic effect. We believe our focus on biologically validated growth factors may facilitate a more efficient development path.

We have a productive scientific platform and are building our portfolio of novel product candidates with the aim of transforming the lives of patients suffering from a wide range of serious diseases, including neuromuscular disorders, cancer, and fibrosis. We have discovered and progressed the development of:

- Apitegromab, an inhibitor of the activation of myostatin, for the treatment of spinal muscular atrophy ("SMA"). We also believe apitegromab could have potential in the treatment of other myostatin-related disorders.
- SRK-181, an inhibitor of the activation of latent transforming growth factor beta-1 ("TGFβ1"), for the treatment of cancers that are resistant to anti-PD-(L)1 antibody therapies.
- Potent and selective inhibitors of the activation of transforming growth factor beta ("TGFβ") in collaboration with Gilead, for the treatment of fibrotic diseases. We are advancing multiple collaboration programs toward product candidate selection.
- Additional discovery and early preclinical programs related to the selective modulation of growth factor signaling.

Our first product candidate, apitegromab (formerly SRK-015), is a selective, fully human, monoclonal antibody that specifically binds to proforms of myostatin, which include promyostatin and latent myostatin, thereby inhibiting activation of the growth factor, myostatin, in skeletal muscle. Apitegromab is being developed as a potential first muscle-directed therapy to address the motor function impairment affecting patients with SMA. The U.S. Food and Drug Administration ("FDA") granted Rare Pediatric Disease designation and Orphan Drug designation to apitegromab for

the treatment of SMA in August 2020 and March 2018, respectively. In March 2021, the European Medicines Agency ("EMA") granted Priority Medicines (PRIME) designation to apitegromab for the treatment of SMA.

On April 6, 2021, we announced positive top-line data for the 12-month treatment period of our TOPAZ Phase 2 proof-of-concept trial, which enrolled 58 patients with Type 2 and Type 3 SMA across 16 study sites in the United States and Europe. The trial evaluated the safety and efficacy of intravenous apitegromab dosed every four weeks (Q4W) over a 12-month treatment period. Four patients (one in Cohort 2 and three in Cohort 3) each missed three consecutive doses of apitegromab over the course of the 12-month treatment period due to COVID-19-related site access restrictions and were excluded from the prespecified intent-to-treat primary analysis.

Cohort 1: This open-label, single-arm cohort enrolled 23 patients with ambulatory Type 3 SMA. Patients were treated with 20 mg/kg of apitegromab either as a monotherapy or in conjunction with an approved SMN upregulator therapy (nusinersen). The primary objectives of Cohort 1 were to assess safety and the mean change from baseline in Revised Hammersmith Scale following 12 months of treatment.

Cohort 1 (Intent-to-treat population)	**Apitegromab 20 mg/kg monotherapy (n=11)**	**Apitegromab 20 mg/kg + nusinersen (n=12)**	**Apitegromab pooled (n=23)**
Mean change from baseline in RHS score (95% CI)	-0.4 (-3.9, +3.1)	-0.3 (-2.0, +1.4)	-0.3 (-2.1, +1.4)
% of patients attaining ≥0-point increase in RHS score	6/11 (55%)	7/12 (58%)	13/23 (57%)
% of patients attaining ≥1-point increase in RHS score	4/11 (36%)	5/12 (42%)	9/23 (39%)
% of patients attaining ≥3-point increase in RHS score	3/11 (27%)	2/12 (17%)	5/23 (22%)
% of patients attaining ≥5-point increase in RHS score	1/11 (9%)	0/12 (0%)	1/23 (4%)

Cohort 2: This open-label, single-arm cohort enrolled 15 patients with Type 2 or non-ambulatory Type 3 SMA and who were already receiving treatment with an approved SMN upregulator (nusinersen) initiated at age five years or older. One patient missed three consecutive doses of apitegromab due to COVID-19-related site access restrictions and was excluded from the prespecified intent-to-treat primary analysis. The primary objectives of the cohort were to assess safety and the mean change from baseline in HFMSE following 12 months of treatment.

One patient in Cohort 2 was identified as having received concomitant treatment with an acetylcholinesterase inhibitor before and during the study, which was not permitted by the trial protocol. This patient experienced a 7-point decline in HFMSE score at the 12-month timepoint. In the per protocol analysis conducted in accordance with the prespecified approach, which excludes this patient as well as the patient who missed three consecutive doses due to COVID-19-related site access restrictions, the mean change from baseline in HFMSE score for Cohort 2 was a 1.2-point improvement.

Cohort 2	**Apitegromab 20 mg/kg + nusinersen**	
	Intent-to-treat (n=14)	**Per Protocol (n=13)**
Mean change from baseline in HFMSE score (95% CI)	+0.6 (-1.4, +2.7)	+1.2 (-0.5, 2.9)
% of patients attaining ≥1 point increase in HFMSE score	9/14 (64%)	9/13 (69%)
% of patients attaining ≥3 point increase in HFMSE score	4/14 (29%)	4/13 (31%)
% of patients attaining ≥5 point increase in HFMSE score	2/14 (14%)	2/13 (15%)

Cohort 3: This randomized, double-blind, parallel arm portion of the trial enrolled patients with Type 2 SMA who had initiated treatment with an approved SMN upregulator (nusinersen) before five years of age. Twenty patients were randomized in a 1:1 ratio to receive the low dose (apitegromab 2 mg /kg Q4W) or high dose (apitegromab 20 mg/kg Q4W); both treatment arms were in conjunction with an approved SMN upregulator therapy (nusinersen). Three patients (two in high-dose arm and one in low-dose arm) each missed three consecutive doses of apitegromab due to COVID-19-related site access restrictions and were excluded from the prespecified intent-to-treat primary analysis. The primary objectives of the cohort were to assess safety and the mean change from baseline in HFMSE following 12 months of treatment.

Cohort 3 (Intent-to-treat population)	Apitegromab 20 mg/kg + nusinersen (n=8)	Apitegromab 2 mg/kg + nusinersen (n=9)	Apitegromab pooled (n=17)
Mean change from baseline in HFMSE score (95% CI)	+7.1 (+1.8, +12.5)	+5.3 (-1.5, +12.2)	+6.2 (+2.2, +10.1)
% of patients attaining ≥1-point increase in HFMSE score	7/8 (88%)	7/9 (78%)	14/17 (82%)
% of patients attaining ≥3-point increase in HFMSE score	5/8 (63%)	5/9 (56%)	10/17 (59%)
% of patients attaining ≥5-point increase in HFMSE score	5/8 (63%)	5/9 (56%)	10/17 (59%)
% of patients attaining >10-point increase in HFMSE score	3/8 (38%)	3/9 (33%)	6/17 (35%)

Dose response was observed; the 20 mg/kg dose achieved numerically greater mean improvements from baseline in HFMSE scores than the 2 mg/kg dose across all assessed timepoints in the 12-month treatment period. The clinically observed dose response was consistent with the pharmacodynamic (target engagement) results. Both the 20 mg/kg and 2 mg/kg doses yielded high levels of target engagement (>100-fold increase from baseline), but the 20 mg/kg dose led to a relatively higher absolute level of target engagement.

Overall safety and tolerability profile:

- Incidence and severity of adverse events were consistent with the underlying patient population and background therapy.
- Five most frequently reported TEAEs: Headache (24%), pyrexia (22%), upper respiratory tract infection (22%), cough (22%), and nasopharyngitis (21%).
- Five patients experienced a serious treatment-emergent adverse event, all assessed by the respective trial investigator as unrelated to apitegromab:
    - One patient treated with 2 mg/kg dose (Cohort 3) hospitalized due to adenoidal hypertrophy and tonsillar hypertrophy to perform scheduled adenotonsillectomy (Grade 2). Event resolved without sequelae.
    - Two patients treated with 20 mg/kg dose (both Cohort 1) with gait inability considered a significant disability (both Grade 3). Events remain ongoing.
    - One patient treated with 20 mg/kg dose (Cohort 1) hospitalized with post lumbar puncture syndrome (Grade 2). Event resolved without sequelae.
    - One patient treated with 20 mg/kg dose (Cohort 1) hospitalized due to viral upper respiratory tract infection (Grade 2). Event resolved without sequelae.
- One patient (Cohort 1) presented with a non-serious Grade 3 post lumbar puncture syndrome; assessed by trial investigator as unrelated to apitegromab. Event resolved without sequelae.
- One patient (Cohort 1) discontinued from the trial due to Grade 2 muscle fatigue that started prior to initiation of dosing with study drug; assessed by the trial investigator as unrelated to apitegromab.

- Anti-drug antibodies (ADA) were present at low titers following apitegromab treatment in three out of the 58 enrolled patients. No apparent impact on drug exposure was observed and was not associated with any hypersensitivity reactions.

All 57 patients who completed the 12-month TOPAZ trial elected to opt into the extension phase, which is ongoing.

Subject to feedback from regulatory agencies, a Phase 3 trial evaluating apitegromab as an add-on to background SMN upregulator therapy in patients with non-ambulatory Type 2 and Type 3 SMA is anticipated to initiate by the end of 2021. The non-ambulatory Type 2 and Type 3 patient population is where apitegromab demonstrated the largest increases in motor function (HFMSE scores) as add-on to nusinersen in the TOPAZ trial. Patients with non-ambulatory Type 2 and Type 3 SMA represent approximately two-thirds of the overall prevalent SMA patient population.

We have identified multiple other diseases for which the selective inhibition of the activation of myostatin may offer therapeutic benefit, including additional patient populations in SMA (such as Type 1 SMA and ambulatory Type 3 SMA) and indications outside of SMA, such as Becker Muscular Dystrophy (BMD).

Our second product candidate, SRK-181, is being developed for the treatment of cancers that are resistant to checkpoint inhibitor (“CPI”) therapies, such as anti-PD-1 or anti-PD-L1 antibody therapies. SRK-181 is a selective inhibitor of the activation of latent TGFβ1 that is being investigated in our DRAGON Phase 1 proof-of-concept clinical trial in patients with locally advanced or metastatic solid tumors that exhibit primary resistance to anti-PD-(L)1 antibodies. This two-part trial consists of a dose escalation portion (Part A) and a dose expansion portion (Part B). Part A is evaluating SRK-181 as a single-agent and in combination with an approved anti-PD-(L)1 therapy and Part B will evaluate SRK-181 in combination with an approved anti-PD-(L)1 therapy across multiple solid tumor types, including urothelial carcinoma, cutaneous melanoma, non-small cell lung cancer, and other solid tumors. We are enrolling patients and progressing dose escalation in Part A of the trial and expect to advance to Part B of the trial in mid-2021 with initial clinical response and safety data from Part A anticipated by the end of 2021.

Utilizing our proprietary platform, we have multiple early stage and preclinical programs directed against targets that are known to be important in serious diseases, including neuromuscular disorders, cancer and fibrosis. We are discovering and generating selective and differentiated monoclonal antibodies against difficult targets by 1) applying our structural insights and antibody discovery expertise, 2) prioritizing human biology, and 3) embedding translational thinking early in the research and development process.

Since inception, we have incurred significant operating losses. Our net losses were $27.7 million and $17.1 million for the three months ended March 31, 2021 and 2020, respectively. As March 31, 2021, we had an accumulated deficit of $272.0 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future. In addition, we anticipate that our expenses will increase in connection with our ongoing activities, as we:

- continue development activities for apitegromab, including the ongoing extension phase of our TOPAZ Phase 2 clinical trial and preparations and conduct of our Phase 3 clinical trial program in SMA, and associated drug supply;
- continue research and development activities for SRK-181, including the conduct of our DRAGON Phase 1 clinical trial;
- continue research and development activities to support our collaboration with Gilead;
- continue to discover, validate and develop additional product candidates through the use of our proprietary platform;
- maintain, expand and protect our intellectual property portfolio;
- hire additional research, development and business personnel; and
- continue to build the infrastructure to support our operations as a public company.

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products in the near future. If we successfully complete clinical development and obtain regulatory approval for apitegromab, SRK-181 or any of our future product candidates, we may generate revenue in the future from product sales. In addition, if we obtain regulatory approval for apitegromab, SRK-181 or any of our future product candidates,

we expect to incur significant expenses related to developing our commercialization capability to support product sales, marketing and distribution activities.

COVID-19 Pandemic

In March 2020, the World Health Organization declared the outbreak of a novel coronavirus, or COVID-19, as a pandemic (the "COVID-19 pandemic"), which continues to spread throughout the U.S. and worldwide. We could be materially and adversely affected by the risks, or the public perception of the risks, related to an epidemic, pandemic, outbreak, or other public health crisis, such as the COVID-19 pandemic. The ultimate extent of the impact of any epidemic, pandemic, outbreak, or other public health crisis on our business, financial condition and results of operations will depend on future developments, which are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of such epidemic, pandemic, outbreak, or other public health crisis and actions taken to contain or prevent the further spread, including the development and deployment of any vaccine program. Accordingly, we cannot predict the extent to which our business, including our clinical trials, financial condition and results of operations will be affected. As a result of the COVID-19 pandemic, we have experienced disruptions that have impacted our business, preclinical studies and clinical trials, including disruptions or restrictions on our ability to access and monitor certain clinical trial sites, restrictions on clinical trial participants' ability to access our clinical trial sites and delays in enrollment. Some clinical trial participants have missed or experienced delays in receiving doses of study drug and completing their clinical trial assessments. For example, four patients (one in Cohort 2 and three in Cohort 3) of the TOPAZ clinical trial each missed three doses of apitegromab over the course of the 12-month treatment period due to COVID-19-related site access restrictions. This has affected our clinical trials and could result in further impacts, including delays in or adverse impacts to data readouts from our clinical trials, delays in our ability to identify and enroll patients in current or future clinical trials and decisions by enrolled patients to discontinue from our clinical trials due to COVID-19 related concerns. While our laboratory operations have resumed to near-normal capacity, we may continue to experience challenges in procuring materials and supplies in a consistently timely manner due to COVID-19 related supply chain issues. Some of our third party manufacturers have diverted resources or manufacturing capacity to accommodate the development or manufacture of COVID-19 coronavirus vaccines. Although this has not had an impact on our ability to produce sufficient quantities of apitegromab or SRK-181 for our clinical trials, we continually work closely with our third party manufacturers to mitigate potential impacts to our clinical supply chain. In addition, delays in the development of COVID-19 vaccines or the deployment of vaccines which are approved or otherwise authorized for emergency use, a recurrence or "subsequent waves" of COVID-19 cases, or the discovery of vaccine-resistant COVID-19 variants could cause other widespread or more severe impacts. We continue to monitor developments as we deal with the disruptions and uncertainties relating to the COVID-19 pandemic.

Financial Operations Overview

Revenue

No revenues have been recorded from the sale of any commercial product. Revenue generation activities have been limited to collaborations containing research services and the issuance of a license. Currently, revenue is being recognized related to the Gilead Collaboration Agreement which was executed on December 19, 2018 (the "Effective Date"), and we began recognizing associated revenue in 2019. Under the Gilead Collaboration Agreement, Gilead has exclusive options to license worldwide rights to product candidates that emerge from three of the Company's TGFβ programs (each a "Gilead Program"). Each option may be exercised by Gilead at any time from the Effective Date through a date that is 90 days following the expiration of the Research Collaboration Term for a given Gilead Program (no later than March 19, 2022), or until termination of the Gilead Program, whichever is earlier (the "Option Exercise Period").

Revenue associated with the research and development and license performance obligations relating to the Gilead Programs is recognized as revenue as the research and development services are provided using an input method. The input method is based on the costs incurred on each Gilead Program and the costs expected to be incurred in the future to satisfy the performance obligation. The transfer of control occurs over time. In management's judgment, this input method is the best measure of progress towards satisfying the performance obligations. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition. The estimate of remaining costs is highly subjective, as the research is novel, therefore efforts to be successful may be

significantly different than the estimated costs made at the balance sheet date. The amounts received that have not yet been recognized as revenue are recorded in deferred revenue on our consolidated balance sheet. We expect to recognize the deferred revenue related to the research and development services based on the cost input method described above, over the remaining research term for each respective Gilead Program, which is up to three years from the execution of the agreement. Each research term is dependent on the timing of Gilead either exercising its options for the Gilead Programs or terminating further development on the Gilead Programs prior to the expiration date of the research term. The deferred revenue related to the material rights of $33.2 million will be recognized as options are exercised by Gilead or at the conclusion of the Option Exercise Period.

Operating Expenses

Research and Development

Research and development expenses consist primarily of costs incurred for our research and development activities, including our product candidate discovery efforts, preclinical studies, manufacturing, and clinical trials under our research programs, which include:

- employee-related expenses, including salaries, benefits and equity-based compensation expense for our research and development personnel;
- expenses incurred under agreements with third parties that conduct research and development and preclinical activities on our behalf;
- expenses incurred under agreements related to our clinical trials, including the costs for investigative sites and contract research organizations (“CROs”), that conduct our clinical trials;
- manufacturing process-development, manufacturing of clinical supplies and technology-transfer expenses;
- consulting and professional fees related to research and development activities;
- costs of purchasing laboratory supplies and non-capital equipment used in our internal research and development activities;
- costs related to compliance with clinical regulatory requirements; and
- facility costs and other allocated expenses, which include expenses for rent and maintenance of facilities, insurance, depreciation and other supplies.

Research and development costs are expensed as incurred. Costs for certain activities are recognized based on an evaluation of the progress to completion of specific tasks. Nonrefundable advance payments for research and development goods and services to be received in the future from third parties are deferred and capitalized. The capitalized amounts are expensed as the related services are performed.

A significant portion of our research and development costs have been external costs, which we track on a program-by-program basis after a clinical product candidate has been identified. However, we do not allocate our internal research and development expenses, consisting primarily of employee related costs, depreciation and other indirect costs, on a program-by-program basis as they are deployed across multiple projects.

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, as well as the associated clinical trial material requirements. We expect research and development costs to increase for the foreseeable future as our product candidate development programs progress, and we expect to incur additional costs in connection with our research and development activities under our collaboration with Gilead. However, we do not believe that it is possible at this time to accurately project total program-specific expenses through commercialization. There are numerous factors associated with the successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control will impact our clinical development programs and plans.

The successful development of apitegromab, SRK-181 and any future product candidates is uncertain. Accordingly, at this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be

necessary to complete the remainder of the development of apitegromab, SRK-181 and any future product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from the sale of our product candidates, if approved. This is due to the numerous risks and uncertainties associated with developing product candidates, including the uncertainty of:

- the scope, progress, outcome and costs of our preclinical development activities, clinical trials and other research and development activities;
- establishing an appropriate safety profile;
- successful enrollment in and completion of clinical trials, including on account of the COVID-19 pandemic and its impact at clinical trial sites;
- whether our product candidates show safety and efficacy in our clinical trials;
- receipt of marketing approvals from applicable regulatory authorities, if any;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- significant and changing government regulation;
- commercializing the product candidates, if and when approved, whether alone or in collaboration with others; and
- continued acceptable safety profile of the products following any regulatory approval.

A change in the outcome of any of these variables with respect to the development of apitegromab, SRK-181 or any of our future product candidates could significantly change the costs and timing associated with the development of that product candidate.

General and Administrative

General and administrative expenses consist primarily of employee-related expenses, including salaries, benefits and equity-based compensation expenses for personnel in executive, finance, business development, investor relations, legal, information technology and human resources functions. Other significant general and administrative expenses include facility costs not otherwise included in research and development expenses, legal fees relating to patent and corporate matters and fees for accounting, consulting services, and corporate expenses.

We anticipate that our general and administrative expenses will increase in the future as our business expands to support expected growth in research and development activities, including the continued progression of our product candidates through development stages, as we hope to approach marketing and commercialization. These increases will likely include increased costs related to the hiring of additional personnel, as well as fees to outside consultants, among other expenses. We also anticipate continued expenses associated with being a public company, including costs for audit, legal, regulatory and tax-related services, director and officer insurance premiums and investor relations costs.

Other Income (Expense), Net

Other income (expense), net consists primarily of interest income earned on our cash, cash equivalents and marketable securities, and interest expense incurred on our credit facility (the October 2020 Loan and Security Agreement with Oxford Finance LLC and Silicon Valley Bank, further discussed in Note 8 of our consolidated financial statements appearing elsewhere in this report), including amortization of debt discount and debt issuance costs.

Results of Operations

Comparison of the Three Months Ended March 31, 2021 and 2020

The following table summarizes our results of operations for the three months ended March 31, 2021 and 2020 (in thousands, except percentages):

	Three Months Ended March 31,		Change	
	2021	2020	$	%
Revenue	$ 4,708	$ 5,030	$ (322)	(6.4)%
Operating expenses:				
Research and development	22,549	16,902	5,647	33.4 %
General and administrative	9,366	5,822	3,544	60.9 %
Total operating expenses	31,915	22,724	9,191	40.4 %
Loss from operations	(27,207)	(17,694)	(9,513)	53.8 %
Other income (expense), net	(464)	624	(1,088)	(174.4)%
Net loss	$ (27,671)	$ (17,070)	$ (10,601)	62.1 %

Revenue

Revenue was $4.7 million and $5.0 million for the three months ended March 31, 2021 and March 31, 2020, respectively, a decrease of $0.3 million or 6.4%. The revenue for both of these periods was related to the Gilead Collaboration Agreement executed in December 2018. Revenue associated with the research and development and license performance obligations relating to the Gilead Programs is recognized as the research and development services are provided using a cost input method. The decrease in revenue was attributable to the change in progress of the programs period over period. The $47.3 million deferred revenue balance as of March 31, 2021 is comprised of $14.1 million that we expect will be recognized as revenue during the remainder of 2021 and $33.2 million related to material rights that will be recognized as revenue either at the time the options are exercised by Gilead or at the lapse of the Option Exercise Period, March 19, 2022.

Operating Expenses

Research and Development

Research and development expense was $22.5 million and $16.9 million for the three months ended March 31, 2021 and March 31, 2020, respectively, an increase of $5.6 million or 33.4%. The following table summarizes our research and development expense for the three months ended March 31, 2021 and 2020 (in thousands, except percentages):

	Three Months Ended March 31,		Change	
	2021	2020	$	%
External costs by program				
Apitegromab (SRK-015)	$ 6,994	$ 4,200	$ 2,794	66.5 %
SRK-181	2,442	3,994	(1,552)	(38.9)%
Other early development candidates and unallocated costs	973	1,196	(223)	(18.6)%
Total external costs	10,409	9,390	1,019	10.9 %
Internal costs:				
Employee compensation and benefits	7,809	5,424	2,385	44.0 %
Facility and other	4,331	2,088	2,243	107.4 %
Total internal costs	12,140	7,512	4,628	61.6 %
Total research and development expense	$ 22,549	$ 16,902	$ 5,647	33.4 %

The increase in research and development expense was primarily attributable to the following:

- An increase in our external research and development costs of $1.0 million, which primarily consisted of:

  - $2.8 million increase in costs associated with apitegromab, due primarily to costs associated with our clinical drug supply manufacturing; partially offset by
  - $1.6 million decrease in costs associated with SRK-181 primarily due to lower clinical drug supply manufacturing costs compared to the corresponding period in 2020.
- $4.6 million increase in internal research and development costs, which was primarily driven by an increase in employee compensation and benefits costs, associated with increased headcount and related overhead, as we continued to expand our research and development functions in addition to an increase in facility costs due to our new office and laboratory space at 301 Binney Street in Cambridge, Massachusetts.

We expect our research and development expenses to increase as we continue to advance the development of our investigational product candidates, including apitegromab through the extension phase of our TOPAZ Phase 2 clinical trial and preparations and conduct of the Phase 3 clinical trial program in SMA, and SRK-181, through our DRAGON Phase 1 clinical trial. Additionally, we expect to continue to conduct research under the Gilead collaboration. However, as described above in ***COVID-19 Pandemic***, the ultimate extent of the impact of the COVID-19 pandemic on our results of operations will depend on future developments, which are highly uncertain. Accordingly, we cannot fully predict the extent to which our business and results of operations will be affected.

General and Administrative

General and administrative expense was $9.4. million and $5.8 million for the three months ended March 31, 2021 and March 31, 2020, respectively, an increase of $3.6 million or 60.9%. The increase in general and administrative expense was primarily attributable to an increase of $1.9 million in employee compensation and benefits, related to increased headcount, in addition to an increase in facility costs due to our new office and laboratory space at 301 Binney Street in Cambridge, Massachusetts.

We anticipate that our general and administrative expenses will increase in the future as our business expands to support our expected growth in research and development activities, including the continued development of our product candidates. However, as described above in ***COVID-19 Pandemic***, the ultimate extent of the impact of the COVID-19 pandemic on our results of operations will depend on future developments, which are highly uncertain. Accordingly, we cannot fully predict the extent to which our business and results of operations will be affected.

Other Income (Expense), Net

The change in other income (expense), net was primarily attributable to an increase in interest expense related to our Loan and Security Agreement entered into in October 2020, as well as a decrease in income earned on our investment portfolio associated with lower interest rates during the three months ended March 31, 2021, as compared to the three months ended March 31, 2020.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have not generated any product revenue and have incurred significant operating losses and negative cash flows from our operations. We have funded our operations to date primarily with proceeds from the sale of our convertible preferred stock and units in private placements before our IPO, and sale of our common stock through our IPO, to Gilead in an exempt private placement, through a secondary public offering in June 2019, and through a follow-on offering completed in November 2020, as well as payments from our research collaborations and a debt facility entered into in October 2020.

The following table provides information regarding our total cash, cash equivalents and marketable securities at March 31, 2021 and December 31, 2020 (in thousands):

	March 31, 2021	December 31, 2020
Cash and cash equivalents	$ 159,108	$ 160,358
Marketable securities	155,581	180,673
Total cash, cash equivalents and marketable securities	$ 314,689	$ 341,031

During the three months ended March 31, 2021, our cash, cash equivalents and marketable securities balance decreased by approximately $26.3 million. The decrease was primarily due to cash used to operate our business, including payments related to, among other things, research and development and general and administrative expenses as we continued to invest in our primary product candidates and supported our internal research and development efforts, capital purchases, and interest payments on our debt, partially offset by receipts from stock option exercises.

In October 2020, we entered into an underwriting agreement relating to the issuance and sale of an aggregate of 3,717,948 shares of our common stock at $39.00 per share and pre-funded warrants to purchase 2,179,487 shares of our common stock. The price of each pre-funded warrant was $38.9999, which equals the per share public offering price for the common shares less the $0.0001 exercise price for each such pre-funded warrant. Total gross proceeds of the transaction was $230.0 million. The offering closed on November 2, 2020 and we received approximately $215.9 million in net proceeds, after deducting underwriting discounts and commissions and estimated offering expenses.

In October 2020, we entered into a Loan and Security Agreement (the “Loan and Security Agreement”) with Oxford Finance LLC (“Oxford”) and Silicon Valley Bank (“SVB”) (each, a “Lender” and collectively, the “Lenders”), providing up to $50.0 million of borrowings, of which $25.0 million was advanced on October 16, 2020. The additional $25.0 million under the Loan and Security Agreement will be available to us until December 31, 2021, subject to our achievement of both (i) the dosing of the first patient in a Phase 3 clinical trial for apitegromab and (ii) the dosing of the first patient in Part B of the DRAGON Phase 1 clinical trial for SRK-181.

In June and July 2019, we sold 3,450,000 shares of our common stock through an underwritten public offering. As a result of the offering, we received aggregate net proceeds, after underwriting discounts and commissions and other offering expenses, of approximately $48.3 million.

In December 2018, we entered into the Gilead Collaboration Agreement pursuant to which we will conduct research and pre-clinical development activities relating to the diagnosis, treatment, cure, mitigation or prevention of diseases, disorders or conditions, other than in the field of oncology in accordance with a pre-determined research plan. Pursuant to the Gilead Collaboration Agreement, Gilead made non-refundable payments of $80.0 million, including an upfront payment and an equity investment. As mentioned above, in December 2019, we achieved a $25.0 million preclinical milestone for the successful demonstration of efficacy in preclinical in vivo proof-of-concept studies, and subsequently received the associated payment in January 2020.

Cash Flows

The following table provides information regarding our cash flows for the three months ended March 31, 2021 and 2020 (in thousands):

	Three Months Ended March 31,	
	2021	2020
Net cash (used in) provided by operating activities	$ (26,544)	$ 2,636
Net cash provided by investing activities	22,557	56,091
Net cash provided by financing activities	2,737	399
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (1,250)	$ 59,126

Net Cash (Used in) Provided by Operating Activities

Net cash used in operating activities was $26.5 million for the three months ended March 31, 2021, and consisted of our net loss of $27.7 million, changes in our assets and liabilities of $6.0 million, partially offset by non-cash adjustments of $7.2 million. The changes in our assets and liabilities includes a $4.7 million change in deferred revenue related to the Gilead collaboration. The non-cash adjustments are primarily from equity-based compensation.

Net cash provided by operating activities was $2.6 million for the three months ended March 31, 2020 and consisted of the $25 million of cash received from Gilead in January 2020 from the preclinical milestone that was achieved in December 2019, non-cash adjustments of $2.7 million, primarily from equity-based compensation, partially offset by our net loss of $17.1 million and changes in our remaining assets and liabilities of $8.0 million, of which $5.0 million is a change in deferred revenue related to the Gilead collaboration.

Net Cash Provided by Investing Activities

Net cash provided by investing activities was $22.6 million for the three months ended March 31, 2021 compared to net cash provided by investing activities of $56.1 million for the three months ended March 31, 2020. Net cash provided by investing activities for both periods was primarily associated with transactions involving our marketable securities.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $2.7 million for the three months ended March 31, 2021, compared to $0.4 million for the three months ended March 31, 2020. Net cash provided by financing activities for both periods was primarily attributable to proceeds from stock option exercises.

Funding Requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development for, continue and initiate later stage clinical trials for, continue to develop and optimize our manufacturing processes for, and seek marketing approval for, our product candidates, including apitegromab and SRK-181, and any of our future product candidates. In addition, if we obtain marketing approval for apitegromab, SRK-181 or any of our future product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Furthermore, we expect to continue to incur costs associated with operating as a public company.

We expect that our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements into 2023. However, we will require additional capital in order to complete clinical development for each of our current programs. We have based this estimate on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the costs and timing of developing our product candidates, apitegromab and SRK-181, including the extension phase of our TOPAZ Phase 2 clinical trial and Phase 3 clinical program for apitegromab in SMA, the DRAGON Phase 1 clinical trial for SRK-181, and the costs and timing of conducting future clinical trials, including on account of the COVID-19 pandemic and its impact at clinical trial sites;
- the costs of future manufacturing of apitegromab, SRK-181 and any other product candidates;
- the scope, progress, results and costs of discovery, preclinical development, laboratory testing and clinical trials for other potential product candidates we may develop, if any;
- the costs of identifying and developing, or in-licensing or acquiring, additional product candidates and technologies;
- the costs, timing and outcome of regulatory review of our product candidates;
- our ability to establish and maintain collaborations on favorable terms, if at all;

- the achievement of milestones or occurrence of other developments that trigger payments under any collaboration agreements, license agreements, or other agreements we might have at such time;
- the costs of seeking marketing approvals for our product candidates that successfully complete clinical trials, if any;
- the costs and timing of future commercialization activities, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, obtaining, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our headcount growth and associated costs as we expand our business operations and research and development activities;
- the costs of expanding our infrastructure and facilities to accommodate our growing employee base, including adding equipment and physical infrastructure to support our research and development; and
- the costs of operating as a public company.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, common stockholder ownership interests may be diluted, and the terms of these securities may include liquidation or other preferences that could adversely affect the rights of a common stockholder. Additional debt financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, that could adversely impact our ability to conduct our business.

If we raise funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. Market volatility resulting from the COVID-19 pandemic or other factors could also adversely impact our ability to access capital as and when needed. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Critical Accounting Policies and Use of Estimates

This management's discussion and analysis is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these consolidated financial statements requires us to make judgments and estimates that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgements 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. On an ongoing basis, we evaluate our judgments and estimates in light of changes in circumstances, facts and experience. The effects of material revisions in estimates, if any, will be reflected in the

consolidated financial statements prospectively from the date of change in estimates. Our actual results may differ from these estimates under different assumptions or conditions.

There have been no material changes to our critical accounting policies from those described in Part II, Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in our Annual Report on Form 10-K for the year ended December 31, 2020.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under applicable SEC rules.

Recent Accounting Pronouncements

We have reviewed all recently issued standards and have determined that they will not have a material impact on our financial statements or do not otherwise apply to our operations.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and are not required to provide the information required under this item.

Item 4. Controls and Procedures

Management’s Evaluation of our Disclosure Controls and Procedures

We maintain “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission’s rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal accounting officer, as appropriate to allow timely decisions regarding required disclosure. Our 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. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their control objectives.

Our management, with the participation of our chief executive officer (principal executive officer) and chief financial officer (principal financial officer) has evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2021, the end of the period covered by this Quarterly Report. Based upon such evaluation, our chief executive officer and chief financial officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of such date. We continue to review and document our disclosure controls and procedures, including our internal controls and procedures for financial reporting, and may from time to time make changes aimed at enhancing their effectiveness and to ensure that our systems evolve with our business.

Changes in Internal Controls Over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended March 31, 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Part II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we are subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Although the results of litigation and claims cannot be predicted with certainty, as of the date of this Quarterly Report, we do not believe we are party to any claim or litigation the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors

Careful consideration should be given to the following risk factors, together with all other information set forth in this Quarterly Report on Form 10-Q ("Quarterly Report"), including our consolidated financial statements and related notes, and "Management's Discussion and Analysis of Financial Condition and Results of Operations," and in other documents that we file with the Securities and Exchange Commission (the "SEC"), in evaluating Scholar Rock Holding Corporation and our subsidiaries (collectively, the "Company") and our business, before investing in our common stock. Investing in our common stock involves a high degree of risk. If any of the following risks and uncertainties actually occurs, our business, prospects, financial condition and results of operations could be materially and adversely affected. The market price of our common stock could decline if one or more of these risks or uncertainties were to occur, which may cause you to lose all or part of the money you paid to buy our common stock. The risk factors described below disclose both material and other risks, and are not intended to be exhaustive and are not the only risks facing the Company. New risk factors can emerge from time to time, and it is not possible to predict the impact that any factor or combination of factors may have on our business, prospects, financial condition and results of operations. Certain statements below are forward-looking statements. See "Special Note Regarding Forward-Looking Statements" in this Quarterly Report.

Summary of the Material Risks Associated with Our Business

Our business is subject to numerous risks and uncertainties that you should be aware of before making an investment decision, including those highlighted in the section entitled "Risk Factors." These risks include, but are not limited to, the following:

Risks Related to Product Development and Regulatory Approval

- Product development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of apitegromab, SRK-181, or any future product candidates.
- Our business may be materially and adversely affected by pandemics such as the ongoing COVID-19 pandemic. The COVID-19 pandemic has had, and will likely continue to have, an impact on our business and operations.
- The results of preclinical studies and early-stage clinical trials may not be predictive of future results. Success of a product candidate in an early-stage clinical trial may not be replicated in later-stage clinical trials.
- Interim and preliminary results from our clinical trials that we announce or publish from time to time may change (e.g. from positive efficacy results to poor or negative efficacy results) as more patient data become available and are subject to additional audit, validation and verification procedures that could result in material changes in the final data.
- The data from our clinical trials, including from any future clinical trials conducted by us or any of our collaborators, may reveal significant adverse events not seen in our preclinical studies or earlier clinical trials and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates.
- We rely on third parties to conduct our clinical trials and to conduct certain aspects of our preclinical studies. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or comply with legal and regulatory requirements, we may be delayed or unable to receive regulatory approval of or commercialize any potential product candidates, and our business could be materially harmed.

- The regulatory approval process for our product candidates in the U.S., EU and other jurisdictions is currently uncertain and will be lengthy, time-consuming and inherently unpredictable and we may experience significant delays in the clinical development and regulatory approval, if any, of our product candidates.

- The FDA may disagree with our development plan and we may fail to receive or be delayed in receiving regulatory approval of our product candidates.

- We have received Orphan Drug designation from the FDA for apitegromab for the treatment of SMA and the EC granted Orphan Medicinal Product designation to apitegromab for the treatment of SMA. We may seek Orphan Drug designation from regulatory authorities in other jurisdictions for apitegromab and Orphan Drug designation from the FDA, EC or regulatory authorities in other jurisdictions for our future product candidates. In any of these instances, we may not receive the requested designation or we may be unable to realize the benefits associated with Orphan Drug designation, including the potential for market exclusivity.

- Preclinical development is uncertain. Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to develop our product pipeline and receive regulatory approvals or commercialize these programs on a timely basis or at all, which would have an adverse effect on our business.

Risks Related to Manufacturing and Supply

- Because we rely on third-party manufacturing and supply partners, our supply of research and development, preclinical and clinical development materials, and, if approved, commercial materials, may become limited or interrupted or may not be of satisfactory quantity or quality.

Risks Related to Our Business and Operations

- We will need to continue to grow our organization, including our personnel, systems and relationships with third parties, in order to develop our drug candidates.

- Failure by us or any of our employees, independent contractors, consultants, commercial partners or vendors to comply with applicable laws and regulations could negatively affect our business and operations.

- The failure to maintain the Gilead Collaboration Agreement, or the failure of Gilead to perform its obligations under or our failure to achieve certain milestones under the Gilead Collaboration Agreement could negatively impact our business, financial condition, results of operations and prospects.

Risks Related to Intellectual Property

- Our success depends in part on our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.

- We depend on intellectual property licensed from third parties. Failure to comply with our obligations under any of these licenses or termination of any of these licenses could result in the loss of significant rights, which would harm our business.

Risks Related to Our Financial Condition and Capital Requirements

- We have incurred net losses in every year since our inception and anticipate that we will continue to incur net losses in the future.

Risks Related to Our Common Stock

- Our stock price is volatile and various factors could make our stock less attractive to investors.

Risks Related to Product Development and Regulatory Approval

Product development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of apitegromab, SRK-181, or any future product candidates.

To receive the requisite regulatory approvals to commercialize any product candidates, we must demonstrate through extensive clinical trials that our product candidates are safe and effective in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. 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. Differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. Clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to receive marketing approval of their products.

Successful completion of clinical trials is a prerequisite to submitting a biologics license application ("BLA") to the FDA, a Marketing Authorization Application ("MAA") to the EMA, and similar marketing applications to comparable foreign regulatory authorities, for each product candidate and, consequently, the ultimate approval and commercial marketing of any product candidates.

We may experience delays in initiating, progressing or completing our clinical trials. We also may experience numerous unforeseen events during, or as a result of, any clinical trials in process or any future clinical trials that we conduct that could delay or prevent our ability to receive marketing approval or commercialize apitegromab, SRK-181 or any future product candidates, including:

- delay or inability to reach agreement with the FDA or comparable foreign regulatory authorities on acceptable clinical trial design;
- any orders from local, state or federal governments or clinical trial site policies resulting from the COVID-19 pandemic that determine essential and non-essential functions and staff, which may impact the ability of site staff to conduct assessments, or result in delays to the conduct of the assessments, as part of our clinical trial protocols, or the ability to enter assessment results into clinical trial databases in a timely manner;
- regulators, institutional review boards ("IRBs") or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective Contract Research Organizations ("CROs"), the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- failure by our collaborators to provide us with an adequate and timely supply of product that complies with the applicable quality and regulatory requirements for a combination trial;
- collaborators may provide insufficient funding for a clinical trial program, delay or stop a clinical trial, abandon a product candidate or clinical trial program, repeat or conduct new clinical trials or require a new formulation of a drug candidate for clinical testing;
- clinical trials of any product candidates may fail to show safety and effectiveness, or produce negative or inconclusive results and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or we may decide to abandon product development programs;
- the number of subjects required for clinical trials of any product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower or more challenging than we anticipate or subjects may drop out of these clinical trials or fail to return for post treatment follow-up at a higher rate than we anticipate;

- challenges in identifying or recruiting sufficient study sites or investigators for clinical trials;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- there may be delays related to the impact of the spread of COVID-19 coronavirus on the FDA's ability to continue its normal operations;
- clinical study sites or clinical investigators may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- we may elect to, or regulators, IRBs or ethics committees may require that we or our investigators, suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- limitations on our or our CROs' ability to access and verify clinical trial data captured at clinical study sites through monitoring and source document verification;
- the cost of clinical trials of a product candidate may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate to initiate or complete a given clinical trial;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators, IRBs or ethics committees to suspend or terminate the trials, or reports from clinical testing of other therapies may raise safety or efficacy concerns about our product candidates;
- our failure to establish an appropriate safety profile for a product candidate based on clinical or preclinical data for such product candidate and/or data emerging from other molecules in the same class as our product candidate;
- the FDA, EMA or other regulatory authorities may require us to submit additional data such as long-term toxicology studies, or impose other requirements before permitting us to initiate a clinical trial; and
- evolution in the standard of care or changes in applicable governmental regulations or policies during the development of a product candidate that require amendments to ongoing clinical trials and/or the conduct of additional preclinical studies or clinical trials.
- lack of adequate funding to complete a clinical trial

We could also encounter delays if a clinical trial is placed on clinical hold, suspended or terminated by us, the IRBs of the institutions in which such trials are being conducted, or the FDA, the competent authorities and/or ethics committees of the EU Member States or other regulatory authorities, if a clinical trial is recommended for suspension or termination by the Data Safety Monitoring Board ("DSMB") for such trial, or on account of changes to federal, state, or local laws. A suspension or termination may be imposed 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, EMA, competent authorities and/or ethics committees of the EU Member States or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product or treatment, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Further, the FDA, EMA or other regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials, or may

change the requirements for approval even after they have reviewed and commented on the design for our clinical trials. For example, we anticipate some of our future trials to, in part, utilize an open-label trial design, and our ongoing DRAGON Phase 1 clinical trial for SRK-181 in cancer immunotherapy and our ongoing TOPAZ Phase 2 clinical trial for apitegromab in Type 2 and Type 3 SMA, in part, utilize an open-label trial design. An open-label trial is one where both the patient and investigator know whether the patient is receiving the test article or either an existing approved drug or placebo. Open-label trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label studies are aware that they are receiving treatment. Open-label trials may be subject to a patient bias, for example if patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. Open-label trials also 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. The potential sources of bias in clinical trials as a result of open-label design may not be adequately mitigated and may cause any of our trials that utilize such design to fail and additional trials may be necessary to support future marketing applications. In addition, other types of trials (including randomized, double-blind, parallel arm studies), particularly if smaller in size or if limited to one study, are also subject to potential sources of bias and limitations that may exaggerate any therapeutic effect or falsely identify a positive efficacy signal**,** or conversely, fail to detect an efficacy signal when in fact there may actually be a positive therapeutic effect. Further, the FDA, EMA or other regulatory authorities may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials.

Our product development costs will increase if we experience delays in clinical testing or marketing approvals. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations. Any delays in our clinical development programs may harm our business, financial condition and results of operations significantly.

Our business may be materially and adversely affected by pandemics such as the ongoing COVID-19 pandemic. The COVID-19 pandemic has had, and will likely continue to have, an impact on our business and operations.

The ongoing COVID-19 pandemic is evolving, continues to spread globally, and to date has led to the implementation of various responses, including government-imposed quarantines, closure of non-essential business, work-from-home directives, travel restrictions, physical distancing, shelter-in-place orders and other public health safety measures. These measures have had and continue to have a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. In response to the COVID-19 pandemic, many of our employees are continuing their work remotely outside of our offices. Additionally, our laboratory operations have been reduced since the declaration of the pandemic and our research activities will continue to be impacted until our laboratory operations are able to return to normal levels of operation that existed prior to the COVID-19 pandemic. We rely on third party manufacturers to manufacture apitegromab and SRK-181. Three vaccines for COVID-19 were granted Emergency Use Authorization by the FDA in late 2020 and early 2021, and more are likely to be authorized in the coming months. The resultant demand for vaccines and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, may make it more difficult to obtain materials or manufacturing slots needed for apitegromab or SRK-181. If any of our third party manufacturers is adversely impacted by the COVID-19 pandemic or if they divert resources or manufacturing capacity to accommodate the development or manufacture of a COVID-19 coronavirus vaccine, our supply chain may be disrupted, limiting our ability to supply apitegromab or SRK-181 for our clinical trials. As a result of the COVID-19 pandemic, we have experienced, and may continue to experience, disruptions that impact our business, preclinical studies and clinical trials.

Our clinical trials include sites located in regions that have been afflicted by the COVID-19 coronavirus and many sites have instituted policies regarding operations as a result of the COVID-19 pandemic. Some factors from the COVID-19 pandemic that could adversely affect enrollment in, as well as conduct, progress, continuation and completion of our clinical trials include:

- the diversion of healthcare resources away from the conduct of clinical trial matters to focus on COVID-19 pandemic concerns, including the administration of COVID-19 vaccines, which could negatively affect the attention of physicians serving as our clinical trial investigators, the hospitals serving as our clinical trial sites and the hospital staff supporting the conduct of our clinical trials;

- limitations on travel and quarantine requirements that interrupt key trial activities, such as clinical trial site initiations, our ability and the ability of our CROs to access and monitor clinical trial sites, and new clinical trial site policies resulting from the COVID-19 pandemic that determine essential and non-essential functions and staff, which may impact the ability of site staff to conduct assessments, or result in delays to the conduct of the assessments, as part of our clinical trial protocols, or the ability to enter assessment results into clinical trial databases in a timely manner, or that limit the ability of a patient to participate in a clinical trial or delay access to product candidate dosing or assessments;

- patients may be unable or unwilling to participate further (or may have to limit participation, including missing certain scheduled doses of the investigational product) in our clinical trials;

- skipping or delays in product candidate dosing or assessments as part of a clinical trial that could adversely affect clinical trial data readouts, including efficacy and safety results;

- skipping or delays in the administration of background therapies of patients in a clinical trial, such as SMN upregulator therapy for SMA or anti-PD-(L)1 therapy for cancer, or other background care that could adversely affect clinical trial data readouts, including efficacy and safety results;

- interruption in global shipping affecting the transport of clinical trial materials, such as product candidates used in our trials; and

- employee absenteeism or furlough days that delay necessary interactions with local regulators, ethics committees and other important agencies and contractors.

If a patient participating in one of our clinical trials contracts COVID-19 coronavirus, this could negatively impact the data readouts from these trials; for example, the patient may be unable to participate further (or may have to limit participation) in our clinical trial, the patient may show a different efficacy assessment than if the patient had not been infected, or such patient could experience an adverse event that could be attributed to our drug product. If a patient participating in any of our clinical trials receives COVID-19 vaccination, it is unknown whether or how the vaccination may impact the data readouts from our clinical trial, such as efficacy and safety. The global outbreak of the COVID-19 coronavirus continues to evolve and the conduct of our trials may be adversely affected, despite efforts to mitigate this impact.

Some clinical trial participants have missed or experienced delays in receiving doses of study drug and completing their clinical trial assessments. For example, as of the TOPAZ Phase 2 twelve-month top-line data readout, four patients in the clinical trial each missed three doses of apitegromab due to COVID-19-related site access restrictions. Additionally, enrollment in the DRAGON Phase 1 clinical study in immuno-oncology has been slower than originally projected due to the travel restrictions imposed in areas affected by the COVID-19 pandemic and where certain clinical trial sites for this study are located. Disruptions and delays resulting from the COVID-19 pandemic could result in additional impacts upon our clinical trials, including delays in or adverse impacts to data readouts (e.g. poor or negative efficacy results or adverse safety signal) from our clinical trials and delays in our ability to identify and enroll patients in current or future clinical trials.

The extent to which the COVID-19 pandemic continues to impact our business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity and duration of the COVID-19 coronavirus and the actions to contain the COVID-19 coronavirus or treat its impact, among others.

Our clinical development strategy depends on the continued use and availability of certain third party approved drug therapies.

Apitegromab and SRK-181 are our two clinical-stage product candidates. Certain patients in our TOPAZ Phase 2 clinical trial are receiving apitegromab in conjunction with an approved SMN upregulator therapy such as nusinersen. These patients are reliant on the continued use and availability of such therapies. If access to an approved SMN upregulator therapy such as nusinersen becomes limited or is unavailable, we may be forced to pause or stop our TOPAZ trial, or the medical condition of patients may be affected which could negatively affect the efficacy and safety results for apitegromab in the trial. We have also initiated the DRAGON Phase 1 clinical trial of SRK-181 in patients with locally advanced or metastatic solid tumors that exhibit primary resistance to anti-PD-(L)1 antibody therapies. Certain patients in this clinical trial will receive SRK-181 in conjunction with an approved anti-PD-(L)1 therapy such as pembrolizumab. If access to the approved anti-PD-(L)1 therapy becomes limited or is unavailable, we may not be able to enroll, or may be delayed in enrolling patients or may be forced to pause or stop our DRAGON Phase 1 clinical trial, or the medical condition of patients may be affected which could negatively affect the efficacy and safety results for SRK-181 in the trial. Any delay or suspension of our clinical trials would significantly and adversely affect our business prospects.

The results of preclinical studies and early-stage clinical trials may not be predictive of future results. Success of a product candidate in an early-stage clinical trial may not be replicated in later-stage trials.

The results of preclinical studies, early-stage and smaller open-label clinical trials may not be predictive of the results of future, later-stage, larger and placebo-controlled clinical trials. Preclinical studies and early-stage clinical trials are primarily designed to study PK and PD, understand the side effects of product candidates, and evaluate various doses and dosing schedules. Our current or future product candidates may demonstrate different chemical, biological and pharmacological properties in patients than they do in laboratory studies or may interact with human biological systems in unforeseen or harmful ways. Product candidates in later-stages of clinical trials may fail to show desired pharmacological properties or produce positive safety and efficacy results despite having progressed through preclinical studies and early-stage clinical trials. We completed a Phase 1 trial for apitegromab in healthy adult volunteers and apitegromab is currently being evaluated in the TOPAZ Phase 2 proof-of-concept trial for the treatment of patients with Type 2 and Type 3 SMA. In April 2021, the Company announced positive twelve-month top-line results from the TOPAZ Phase 2 clinical trial. We also initiated the DRAGON Phase 1 trial for SRK-181 in cancer immunotherapy. We cannot assure you that the DRAGON Phase 1 trial, TOPAZ Phase 2 trial, or any other future clinical trials of SRK-181 or apitegromab, will show positive results. There can be no assurance that any of our current clinical trials will ultimately be successful or support further clinical development of any of our product candidates. There can also be no assurance that any of our future clinical trials will show similar results to our earlier clinical trials or support further development or registration of any of our product candidates. There is a high failure rate for drugs and biologics proceeding through clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical development even after achieving promising results in earlier studies, and any such setbacks in our clinical development could have a material adverse effect on our business and operating results.

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

From time to time, we may publish interim data, including interim top-line results or preliminary results from our clinical trials. Any interim data and other results from our clinical trials may materially change as more patient data become available. Preliminary or top-line results also remain subject to audit, validation and verification procedures that may result in the final data being materially different from the interim and preliminary data we previously published. As a result, interim and preliminary data may not be predictive of final results and should be viewed with caution until the final data are available. We may also arrive at different conclusions, or considerations may qualify such results, once we have received and fully evaluated additional data. For example, in April 2021, we announced twelve-month topline data from our TOPAZ trial of apitegromab. We believe these top-line data support further evaluation of apitegromab in a registrational clinical trial, subject to consultation with the FDA and other regulatory agencies. Differences between preliminary or interim data and final data could adversely affect our business.

The data from our clinical trials, including from any future clinical trials conducted by us or any of our collaborators, may reveal significant adverse events not seen in our preclinical studies or earlier clinical trials and may result in a safety profile or undesirable side effects that could inhibit or limit regulatory approval or market acceptance of any of our product candidates.

If significant adverse events or other side effects are observed in any of our clinical trials, we may have difficulty recruiting patients to our clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of one or more product candidates altogether. Patients in our clinical trials may develop levels of anti-drug antibodies which could limit the potential efficacy of our product candidates or trigger negative autoimmune responses. We, the FDA, the competent authorities and/or ethics committees of the EU Member States or other applicable regulatory authorities, or an IRB may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects or patients in such trials are being exposed to unacceptable health risks or adverse side effects.

Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. The side effects could result in a number of potentially significant negative consequences, including:

- regulatory authorities may refuse to grant market approval to a product candidate or withdraw approvals of such product;
- we may suspend marketing of such product;
- regulatory authorities may require additional warnings on the label for such product;
- we may be required to develop a Risk Evaluation and Mitigation Strategy (“REMS”) for such a product, or if a REMS is already in place, to incorporate additional requirements under the REMS, or to develop a similar strategy as required by a comparable foreign regulatory authority; or
- we may be required to conduct additional post-market studies;
- we could be sued and held liable for harm caused to subjects or patients; or
- our reputation may suffer.

Any of these developments could adversely affect our prospects for receiving or maintaining approval for our product candidates and/or inhibit market acceptance of any approved product and could materially harm our business, financial condition and prospects.

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

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including due to the COVID-19 pandemic. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. The enrollment of patients depends on many factors, including:

- the patient eligibility and exclusion criteria defined in the protocol;
- the size of the patient population required for analysis of the trial’s primary endpoints;
- the willingness or availability of patients to participate in our trials (including due to the COVID-19 pandemic);
- the number and location of participating trial sites;

- the proximity of patients to trial sites and any limitations on travel or access to trial sites (including due to the COVID-19 pandemic);
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop-out of the trials before completion.

For example, we are initially developing apitegromab for the treatment of SMA, a rare disease, affecting an estimated 30,000 to 35,000 patients in the U.S. and Europe. As a result, we may encounter difficulties enrolling patients in our clinical trials for apitegromab due, in part, to the small size of this patient population. In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we 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 in such clinical trial site. Additionally, patients may opt out of participation in clinical trials in favor of treatment with FDA-approved therapies, or therapies approved in the EU or other foreign jurisdictions.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our future clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

We rely on third parties to conduct our clinical trials and certain aspects of our preclinical studies. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or comply with legal and regulatory requirements, we may be delayed or unable to receive regulatory approval of or commercialize apitegromab, SRK-181 or any future product candidates, and our business could be materially harmed.

We depend upon third parties to conduct certain aspects of our preclinical studies and to conduct our clinical trials, under agreements with universities, medical institutions, CROs, strategic partners and others. We often have to negotiate budgets and contracts with such third parties, and if we are unsuccessful or if the negotiations take longer than anticipated, this could result in delays to our development timelines and increased costs.

We rely especially heavily on third parties over the course of our clinical trials, and, as a result, have limited control over the clinical investigators and limited visibility into their day-to-day activities, including with respect to their individual employment policies or compliance with the approved clinical protocol. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with good clinical practice ("GCP") requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to suspend or terminate these trials or perform additional preclinical studies or clinical trials before approving our marketing applications. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP requirements. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in civil

monetary penalties, adverse publicity and civil and criminal sanctions. The FDA and National Institutes of Health recently signaled the government's willingness to begin enforcing these registration and reporting requirements against non-compliant clinical trial sponsors.

Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violate federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting aspects of our preclinical studies or clinical trials will not be our employees and, except for remedies that may be available to us under our agreements with such third parties, we cannot control whether they devote sufficient time and resources to our preclinical studies and clinical trials. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they cannot perform their contractual duties or obligations due to the impacts of the COVID-19 pandemic on their operations or at the sites they are overseeing, if they need to be replaced or if the quality or accuracy of the preclinical or clinical data they obtain is compromised due to the failure to adhere to our protocols or regulatory requirements or for other reasons, our development timelines, including clinical development timelines, may be extended, delayed or terminated and we may not be able to complete development of, receive regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

If any of our relationships with these third-party CROs or others terminate, we may not be able to enter into arrangements with alternative CROs or other third parties or to do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO begins work. As a result, delays may occur, which can materially impact our ability to meet our desired development timelines. Though we carefully manage our relationships with our 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.

The regulatory approval process for our product candidates in the U.S., EU and other jurisdictions is currently uncertain and will be lengthy, time-consuming and inherently unpredictable and we may experience significant delays in the clinical development and regulatory approval, if any, of our product candidates.

The research, testing, manufacturing, labeling, approval, sale, import, export, marketing, promotion and distribution of drug products, including biologics, are subject to extensive regulation by the FDA in the U.S. and other regulatory authorities outside the U.S. We are not permitted to market any biological product in the U.S. until we receive a biologics license from the FDA. We have not previously submitted a BLA to the FDA or similar marketing application to comparable foreign authorities. A BLA must include extensive preclinical and clinical data and supporting information to establish that the product candidate is safe, pure and potent for each desired indication. A BLA must also include significant information regarding the chemistry, manufacturing and controls for the product, and the manufacturing facilities must complete a successful pre-license inspection.

The FDA may seek independent advice from a panel of experts, referred to as an Advisory Committee, on complex or novel issues that may be presented in an application, including issues related to the adequacy of the safety and efficacy data to support approval. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to receive approval of any product candidates that we develop based on the completed clinical trials.

Further, a clinical trial may be suspended or terminated by us, the IRBs for the institutions at which such trials are being conducted, or the FDA, the competent authorities and/or ethics committees of the EU Member States or other regulatory authorities, or recommended for suspension or termination by the DSMB for such trial, due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA, EMA, competent authorities of the EU Member States or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side

effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, the prospects for regulatory approval and commercial prospects for our product candidates will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing any clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue.

The FDA may disagree with our development plan and we may fail to receive or be delayed in receiving regulatory approval of apitegromab, SRK-181 and future product candidates.

FDA approval of a new biologic or drug generally requires dispositive data from two (and in some cases, one) adequate and well-controlled pivotal Phase 3 clinical trials of the biologic or drug in the relevant patient population. Phase 3 clinical trials typically involve hundreds of patients, have significant costs and take years to complete.

The results of our clinical trials may not support approval. Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA, EMA 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, EMA or comparable foreign regulatory authorities that our product candidates are safe and effective for any of their proposed indications;
- the results of clinical trials may not meet the level of statistical significance required by the FDA, EMA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks;
- the FDA, EMA 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 the satisfaction of the FDA, EMA or comparable foreign regulatory authorities to support the submission of a BLA or other comparable submission in foreign jurisdictions or to receive regulatory approval in the U.S. or elsewhere;
- the FDA, competent authorities of the EU Member States 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, EMA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

We have received Orphan Drug designation from the FDA for apitegromab for the treatment of SMA and the EC granted Orphan Medicinal Product designation to apitegromab for the treatment of SMA. We may seek Orphan Drug designation from regulatory authorities in other jurisdictions for apitegromab and Orphan Drug designation from the FDA, EC or regulatory authorities in other jurisdictions for our future product candidates. In any of these instances, we may not receive the requested designation or we may be unable to realize the benefits associated with Orphan Drug designation, including the potential for market exclusivity.

Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if, among other things, it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the U.S., or a patient population greater than 200,000 in the U.S. where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the U.S. In the EU, after a recommendation from the EMA's Committee for Orphan Medicinal Products ("COMP"), the EC grants orphan designation to promote the development of products that are (a) intended for

the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the EU, or (b) for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the medicinal product in the EU would generate sufficient return to justify the necessary investment in developing the medicinal product. Additionally, the orphan designation requires that there is no satisfactory method of diagnosis, prevention or treatment of the condition, or, if such a method exists, the medicinal product must be of significant benefit to those affected by the condition. Any Orphan Drug designation that we are granted for our product candidates in the U.S. or in the EU would not assure Orphan Drug designation of those product candidates in any other jurisdiction. Orphan Drug designation neither shortens the development time or regulatory review time of a product candidate, nor gives the product candidate any advantage in the regulatory review or approval process (other than as discussed below).

In the U.S., Orphan Drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product candidate receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity for that indication. Orphan drug exclusivity means the FDA may not approve another application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity. In the EU, orphan designation entitles a party to scientific assistance regarding necessary tests and trials, financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following grant of marketing authorization for the medicinal product if the criteria for orphan designation continue to be met before the grant of the marketing authorization. This period may be reduced to six years if the Orphan Drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

We have received Orphan Drug designation from the FDA for apitegromab for the treatment of SMA, and following the EMA's COMP's positive opinion, the EC designated apitegromab as an orphan medicinal product for the treatment of SMA. Even if we receive orphan drug exclusivity, the benefit of that exclusivity may be limited if we seek approval for an indication broader than the orphan-designated indication or could be revoked under certain circumstances, for example if the FDA later determines that the request for designation was materially defective or that we are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we receive orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition during the exclusivity period because different drugs with different active moieties can be approved for the same condition, and the same product can be approved for different uses. Also, in the U.S., even after an orphan drug is approved and receives orphan drug exclusivity, the FDA may subsequently approve another drug for the same condition if the FDA concludes that the latter drug is not the same drug, including because it has been shown to be clinically superior to the drug with exclusivity because it is safer, more effective or makes a major contribution to patient care. In the EU, marketing authorization may be granted to a similar medicinal product for the same orphan indication if:

- the second applicant can establish in its application that its medicinal product, although similar to the orphan medicinal product already authorized, is safer, more effective or otherwise clinically superior; or
- the holder of the marketing authorization for the original orphan medicinal product consents to a second orphan medicinal product application; or
- the holder of the marketing authorization for the original orphan medicinal product cannot supply sufficient quantities of orphan medicinal product.

We have received Rare Pediatric Disease designation for apitegromab for the treatment of SMA. However, a marketing application for apitegromab, if approved, may not meet the eligibility criteria for a rare pediatric disease priority review voucher.

We have received Rare Pediatric Disease designation for apitegromab for the treatment of SMA. Designation of a biologic as a product for a rare pediatric disease does not guarantee that a BLA for such biologic will meet the eligibility criteria for a rare pediatric disease priority review voucher at the time the application is approved. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), we will need to request a rare pediatric disease priority review voucher in our

original BLA for apitegromab. The FDA may determine that a BLA for apitegromab, if approved, does not meet the eligibility criteria for a rare pediatric disease priority review voucher, including for the following reasons:

- SMA no longer meets the definition of a rare pediatric disease;
- apitegromab contains an active ingredient (including any ester or salt of the active ingredient) that has been previously approved in an application;
- the BLA is not deemed eligible for priority review;
- the BLA does not rely on clinical data derived from studies examining a pediatric population and dosages of the drug intended for that population; or
- the BLA seeks approval for a different adult indication than the rare pediatric disease for which apitegromab is designated.

The authority for the FDA to award rare pediatric disease priority review vouchers for biologics after September 30, 2024 is currently limited to biologics that receive Rare Pediatric Disease designation on or prior to September 30, 2024, and the FDA may only award rare pediatric disease priority review vouchers through September 30, 2026. If the BLA for apitegromab is not approved on or prior to September 30, 2026 for any reason, it will not be eligible for a priority review voucher. However, it is possible the authority for the FDA to award rare pediatric disease priority review vouchers will be further extended by Congress.

We may seek Breakthrough Therapy designation or Fast Track designation from the FDA or PRIME designation from the EMA for certain of our product candidates, and we may not be successful in receiving such designation, or if received, such designation may not actually lead to a faster development or regulatory review or approval process.

We may seek Breakthrough Therapy designation, Fast Track designation or PRIME designation for certain of our product candidates.

A breakthrough therapy is defined as a product that is intended, alone or in combination with one or more other products, to treat a serious or life threatening disease or condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Products that have been designated as breakthrough therapies are eligible for more frequent interaction and communication between the FDA, EMA and the sponsor, which can help to identify the most efficient path for clinical development, as well as rolling review. Products designated as breakthrough therapies by the FDA may also be eligible for (but are not assured) accelerated approval.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy designation for a product candidate may not result in a faster development process, review or approval compared to products considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the products no longer meet the conditions for qualification and rescind the breakthrough designation.

If a product is intended for the treatment of a serious or life-threatening condition and the product demonstrates the potential to address unmet medical needs for this condition, the product sponsor may apply for Fast Track designation. Products receiving a Fast Track designation are eligible for more frequent interaction and communication with FDA and rolling review. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program.

In March 2021, the EMA granted PRIME designation to apitegromab for the treatment of SMA. The receipt of PRIME designation for apitegromab for the treatment of SMA may not result in a faster development process, review or approval compared to products considered for approval under conventional regulatory agency procedures and does not assure ultimate approval by the EMA.

Receiving and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in receiving or maintaining regulatory approval of our product candidates in other jurisdictions.

Receiving and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to receive or maintain regulatory approval in any other jurisdiction, but a failure or delay in receiving regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in other jurisdictions. Even if the FDA grants marketing approval of a product candidate, the EC, the competent authorities of EU Member States or comparable regulatory authorities in foreign jurisdictions may not approve the manufacturing, marketing and promotion of the product candidate in other countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the U.S., including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the U.S., a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the U.S. have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Receiving foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Even if we receive regulatory approval of any product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

If any of our product candidates are approved, they will be subject to ongoing regulatory requirements, including requirements related to manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, import, export, conduct of post-marketing studies and submission of safety, efficacy and other post-marketing information. In addition, we will be subject to continued compliance with cGMP and GCP requirements for any clinical trials that we conduct post-approval.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA, EU 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 periodic review and inspections to assess compliance with cGMP and adherence to commitments made in any BLA or other marketing application and previous responses to inspection observations. 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.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved uses for which the product may be marketed or contain requirements for potentially costly post-market testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS program as a condition of approval of our product candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with

regulatory requirements may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning letters, untitled letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention or refusal to permit the import or export of our product candidates; and
- permanent injunctions and consent decrees, including the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. Products may be promoted only for their approved indications and in a manner consistent with their FDA-approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of unapproved uses and a company that is found to have improperly promoted unapproved uses may be subject to significant liability.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. or abroad. 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 face enforcement action and our business may be harmed.

Even if a product candidate we develop receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If apitegromab, SRK-181 or any future product candidate we develop receives marketing approval, whether as a single agent or in conjunction with other therapies, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors, and others in the medical community. For example, doctors may deem it sufficient to treat patients with SMA with an SMN upregulator such as nusinersen, and therefore will not be willing to utilize apitegromab in conjunction with such SMN upregulator. If the product candidates we develop do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of any product candidate, if approved for commercial sale, will depend on a number of factors, including:

- efficacy and potential advantages compared to alternative treatments;
- the ability to offer our products, if approved, for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the ability to obtain sufficient third-party coverage and adequate reimbursement; and
- the prevalence and severity of any side effects.

Preclinical development is uncertain. Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to develop our product pipeline and receive regulatory approvals or commercialize these programs on a timely basis or at all, which would have an adverse effect on our business.

We have two product candidates, apitegromab and SRK-181, and may not nominate any other product candidates for any of our programs. Before we can commence clinical trials for any product candidate, we must complete extensive preclinical studies that support our planned INDs in the U.S., or similar applications in other jurisdictions. We cannot be certain of the timely completion or outcome of our preclinical studies and cannot predict if the FDA, EMA or other regulatory authorities will accept our proposed clinical programs or if the outcome of our preclinical studies will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA, the competent authorities and/or ethics committees in the EU Member States or other regulatory authorities allowing clinical trials to begin.

Conducting preclinical testing can be a lengthy, time-consuming and expensive process. The time required for such testing may vary substantially according to the type, complexity and novelty of the program, and can be several years or more per program. Delays associated with programs for which we are conducting preclinical testing and studies, such as on account of interruptions or delays in preclinical studies at laboratories or other institutions due to the COVID-19 pandemic, may cause us to incur additional operating expenses. We also may be affected by delays associated with the preclinical testing and studies of certain programs that are the responsibility of our collaborators or our potential future collaborators over which we have limited or no control. The commencement and rate of completion of preclinical studies for a product candidate may be delayed by many factors, including, for example, challenges in reaching consensus with regulatory agencies regarding the scope of the necessary preclinical study program and/or appropriate preclinical study designs.

Risk Related to Manufacturing and Supply

Because we rely on third-party manufacturing and supply partners, our supply of research and development, preclinical and clinical development materials, and, if approved, commercial materials, may become limited or interrupted or may not be of satisfactory quantity or quality.

We rely on third-party contract manufacturers to manufacture some of our preclinical product candidate supplies and rely on third-party contract manufacturers to manufacture all of our clinical trial product supplies and, if approved, will rely on third-party contract manufacturers to manufacture all of our commercial product supplies, including all of our drug substance, vialing, labeling, and packaging. We do not own manufacturing facilities for producing any clinical trial or commercial product supplies. There can be no assurance that our preclinical, clinical development, and, if approved, commercial product supplies will not be limited or interrupted, including as a result of the COVID-19 pandemic, or that our product supplies will be of satisfactory quality or continue to be available at acceptable prices. For example, we rely on a single source supplier for the manufacture of drug substance for apitegromab and SRK-181, and this supplier also manufactures parts of the COVID-19 vaccine that may be subject to the priorities and allocations authority under the Defense of Production Act of 1950 whereby a contract to manufacture the COVID-19 vaccine could take precedence over any manufacturing we have contracted with this supplier. In addition, the extent to which the COVID-19 pandemic impacts our ability to procure sufficient supplies for the development of apitegromab, SRK-181 or future product candidates will depend on the severity and duration of the spread of the virus, and the actions undertaken to contain the COVID-19 coronavirus or treat its effects. Any replacement of our current drug substance contract manufacturer would require significant resources, lead time and expertise because there may be a limited number of qualified replacements.

The manufacturing process for a product candidate is subject to FDA and foreign regulatory authority review. Suppliers and manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as cGMP. In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, such as due to the COVID-19 pandemic, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third-party, which

we may not be able to do on reasonable terms, if at all. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such skills or technology to another third-party and a feasible alternative may not exist. These factors would increase our reliance on the original manufacturer or require us to obtain a license from such manufacturer in order to have another third-party manufacture our product candidates. If we must change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget.

We expect to continue to rely on third-party manufacturers if we receive regulatory approval for apitegromab, SRK-181 or any future product candidate. To the extent that we have existing, or in the future enter into, manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. If we are unable to obtain or maintain third-party manufacturing for product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully. Our or a third-party's failure to execute on our manufacturing requirements and comply with cGMP could adversely affect our business in a number of ways, including:

- an inability to initiate or continue clinical trials for apitegromab, SRK-181 or of future product candidates under development;
- delay in submitting regulatory applications, or receiving regulatory approvals, for apitegromab, SRK-181 or future product candidates;
- loss of the cooperation of an existing or future collaborator;
- subjecting third-party manufacturing facilities or our manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease distribution or to recall batches of apitegromab, SRK-181 or future product candidates; and
- in the event of approval to market and commercialize apitegromab, SRK-181 or a future product candidate, an inability to meet commercial demands for our products.

In addition, we contract with fill and finishing providers which we believe have the appropriate expertise, facilities and scale to meet our needs. Failure to maintain compliance with cGMP can result in a contractor receiving FDA sanctions, which can impact our ability to operate or lead to delays in any clinical development programs. We believe that our current fill and finish contractors are operating in accordance with cGMP, but we can give no assurance that the FDA, EMA, competent authorities of the EU Member States or other regulatory agencies will not conclude that a lack of compliance exists. In addition, any delay in contracting for fill and finish services, or failure of the contract manufacturer to perform the services as needed, may delay any clinical trials, registration and launches, which could negatively affect our business.

Our reliance on third parties, such as manufacturers and antibody discovery vendors, may subject us to risks relating to manufacturing scale-up and may cause us to undertake substantial obligations, including financial obligations.

In order to continue to conduct later-stage clinical trials with apitegromab, SRK-181 or any of our future product candidates, or, if approved, produce commercial product we will need to manufacture such product candidate in large quantities. We, or any manufacturing partners, may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If we, or any manufacturing partners, are unable to successfully scale-up the manufacture of our

product candidates in sufficient quality and quantity, including as a result of the COVID-19 pandemic, the development, testing, and clinical trials of that product candidate may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not received, which could significantly harm our business.

In addition, we rely, and intend to continue to rely, on third-party entities to conduct certain antibody discovery work based on criteria and specifications provided by us. Certain of our antibody discovery vendors may require us to enter into a license agreement with them or exercise an option in an existing agreement with them for the right to use antibodies discovered by them in humans or for commercial purposes. Such license or other agreements could include substantial milestone payments and royalties to the extent we choose to use an antibody discovered by such vendors. For example, under our Adimab Agreement, upon exercise of the development and option for the research program from which SRK-181 was generated, we paid to Adimab a non-creditable, nonrefundable option exercise fee; and on a Product (as defined in the Adimab Agreement)-by-Product basis, we will pay Adimab upon the achievement of various clinical and regulatory milestone events with total milestone payments not to exceed mid-teen millions in the aggregate for a given Product; for any Product that is commercialized, on a country-by-country and Product-by-Product basis, we are obligated to pay to Adimab a low-to-mid single-digit percentage of annual worldwide net sales of such Product during the applicable royalty period in each country. In addition, if we do not meet our obligations under such license or other agreements, the counterparties may have the ability to terminate the license or other agreements and we could lose the right to use the discovered antibodies, which could significantly and adversely impact our business.

Risks Related to Our Business and Operations

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

As our clinical development plans and strategies continue to develop and expand, we expect we will need to hire additional managerial, clinical development, scientific, regulatory, and administrative personnel. Our ability to compete in the highly competitive oncology and immuno-oncology fields depends upon our ability to attract and retain highly qualified specialized personnel. If apitegromab and SRK-181 approach commercialization, we will also need to hire sales, marketing and other commercial personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our development efforts effectively, including the clinical and regulatory review process for apitegromab, SRK-181, and any future 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.

Our future financial performance and our ability to commercialize apitegromab, SRK-181 and future product candidates, if approved, will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on third parties, advisors and consultants to provide certain services, including clinical research organizations, contract manufacturers and companies focused on antibody development and discovery activities. There can be no assurance that the services of third parties, 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, accuracy or quantity of the services provided is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to receive, or may be substantially delayed in receiving, regulatory approval of apitegromab, SRK-181 or future 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.

We may not be able to attract or retain qualified management and scientific personnel in the future due to the intense competition for a limited number of qualified personnel in the biopharmaceutical space, especially those engaged in oncology and immuno-oncology. Many of the other pharmaceutical companies that we compete against for qualified personnel have greater financial resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than what we have to offer. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize apitegromab, SRK-181 or any future product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Our executives and highly skilled technical and managerial personnel are critical to our business. If we lose key personnel, or if we fail to recruit additional highly skilled personnel, our ability to further develop apitegromab, SRK-181 and identify and develop new or next generation product candidates will be impaired.

Our performance substantially depends on the performance of our management team. The unplanned loss of the services of any of our executives or highly skilled technical and managerial personnel could cause us to incur increased operating expenses and divert senior management resources in searching for replacements. These changes in our organization may have a disruptive impact on our ability to implement our strategy and could have a material adverse effect on our business, internal controls, financial condition and results of operations. Management transition inherently causes some loss of institutional knowledge, which can negatively affect strategy and execution. If we have additional changes to our executives or highly skilled technical and managerial personnel, we may be unable to successfully manage and grow our business, and our results of operations, internal controls and financial condition could suffer as a result. The unplanned loss of the services of our executives or other personnel also could harm our reputation.

Our internal computer systems, or those used by our contract research organizations, or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our existing and future CROs, and other contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. While we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. Our increased reliance on personnel working from home may increase our cyber security risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations or delay necessary interactions with local and federal regulators, ethics committees, manufacturing sites, research or clinical trial sites and other agencies and contractors. For example, the loss of preclinical or clinical data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of apitegromab and SRK-181 and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of apitegromab, SRK-181 and future product candidates could be delayed.

Our employees, independent contractors, 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 illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with the laws and regulations of the FDA, EU Member States, EMA and other similar foreign regulatory bodies; provide true, complete and accurate information to the FDA, EMA and other similar foreign regulatory bodies; comply with manufacturing standards we have established; comply with healthcare fraud and abuse laws in the U.S. and similar foreign fraudulent misconduct laws; or report financial information or data accurately or to disclose unauthorized activities to us. If we receive FDA approval of apitegromab, SRK-181 or any future product candidates and begin commercializing those products in the U.S., our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may

impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter misconduct by our employees, independent contractors, consultants, commercial partners and vendors, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of civil, criminal and administrative penalties, damages, monetary fines, individual imprisonment, disgorgement, possible exclusion from participation in government healthcare programs, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings and the curtailment of our operations, any of which could adversely affect our ability to operate our business, financial condition and results of operations.

Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations.

Changes in statutes, regulations, or the interpretation of existing statutes or regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; (iv) additional record-keeping requirements; or (v) changes to our pricing arrangements, or coverage of or reimbursement for our products. If any such changes were to be imposed, they could adversely affect the operation of our business.

In the U.S., there have been and continue to be a number of legislative and regulatory changes and proposed changes to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (“ACA”) was enacted, which, among other things, has substantially changed the way health care is financed by both governmental and private insurers, and has significantly impacted the U.S. pharmaceutical industry. The ACA, among other things:

- subjects biological products to potential competition by lower cost biosimilars,
- addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected,
- increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations,
- establishes annual fees and taxes on manufacturers of certain branded prescription drugs,
- expands healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, establishes new government investigative powers and enhanced penalties for non-compliance,
- creates a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70% as of January 1, 2019, pursuant to the Bipartisan Budget Act of 2018) point of sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D,
- expands eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers’ Medicaid rebate liability,
- expands the entities eligible for discounts under the PHS Act’s pharmaceutical pricing program, also known as the 340B Drug Pricing Program,
- creates new requirements to report financial arrangements with physicians and teaching hospitals, commonly referred to as the Physician Payments Sunshine Act,

- creates a new requirement to annually report the identity and quantity of drug samples that manufacturers and authorized distributors of record provide to physicians,
- creates a new Patient Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research, and
- establishes the Center for Medicare and Medicaid Innovation at the Centers for Medicare & Medicaid Services ("CMS") to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Some of the provisions of the ACA have been subject to judicial challenges as well as efforts to repeal, replace or otherwise modify them or to alter their interpretation or implementation. For example, the Tax Cuts and Jobs Act of 2017 ("Tax Act"), includes a provision that eliminated the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year, commonly referred to as the "individual mandate," effective January 1, 2019. Further, The Bipartisan Budget Act of 2018 ("BBA"), among other things, amends the Medicare statute, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole" by raising the manufacturer discount under the Medicare Part D coverage gap discount program to 70% (as of January 1, 2019). Currently, the Supreme Court is considering whether the Affordable Care Act's individual mandate, post-repeal of its associated tax penalty, is unconstitutional, and, if so, whether the remaining provisions of the Affordable Care Act are inseverable from the mandate. A ruling is expected by mid-2021 and could produce any of a number of results, including invalidation of the Affordable Care Act in its entirety if there is a finding of inseverability. It is unclear how the ultimate decision in this case, or other efforts to repeal, replace or otherwise modify, or invalidate, the Affordable Care Act or its implementing regulations, or portions thereof, will affect our business. Additional legislative changes, regulatory changes and judicial challenges related to the ACA remain possible. We cannot predict what effect further changes related to the ACA, including under the Biden administration, would have on our business.

Other legislative changes have been proposed and adopted in the U.S. since the ACA was enacted. For example, on August 2, 2011, the Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals for spending reductions. The Joint Selection Committee on Deficit Reduction did not achieve a targeted deficit reduction, which triggered the legislation's automatic reduction to several government programs. In concert with subsequent legislation, this includes aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year through 2030. However, pursuant to the Coronavirus Aid, Relief and Economy Security Act ("CARES Act"), and subsequent legislation, these Medicare sequester reductions will be suspended from May 1, 2020 through December 31, 2021 due to the COVID-19 pandemic. The American Taxpayer Relief Act of 2012 also reduced Medicare payments to several types of health care providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years, among other things.

Additionally, there has been increasing legislative, regulatory, and enforcement interest in the United States with respect to drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. For example, on November 20, 2020, CMS issued an interim final rule to implement a "Most Favored Nation" demonstration project to test Medicare Part B reimbursement of certain separately payable drugs and biologicals based on international reference prices. The rule has become subject to judicial challenges, and federal courts have enjoined the rule at this time, and CMS has announced it will not proceed to implement the rule without further rulemaking. The Most Favored Nation model would subject certain drugs or biologicals identified by CMS as having the highest annual Medicare Part B spending to an alternative payment methodology based on international reference prices, with the list of products to be updated annually to add more products and products not to be removed absent limited circumstances. There has also been proposed legislation that would establish an international reference price-based Medicare Part B drug and biological payment methodology.

In addition, there have been changes related to Medicare Part B reimbursement for drugs purchased under the 340B drug pricing program. In 2018, CMS implemented a reduction in reimbursement for Medicare Part B drugs obtained under the 340B program from Average Sales Price (ASP) +6% to ASP -22.5%. This reduction has been challenged in court,

but, to date, the challenge has been unsuccessful. CMS has indicated that it will continue to evaluate Medicare Part B reimbursement for 340B-purchased drugs.

Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including by imposing price or patient assistance constraints, restrictions on certain product access, marketing cost disclosure and other transparency measures, and, in some cases, measures designed to encourage importation of pharmaceutical products from other countries and bulk purchasing.

It is possible that the ACA, as currently enacted or as it may be amended or otherwise modified in the future, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare or other healthcare funding, more rigorous coverage criteria, or new payment methodologies or otherwise affect the prices we may obtain for any of our product candidates for which we may receive regulatory approval. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from commercial payors. We cannot predict the reform initiatives that may be adopted in the future or whether initiatives that have been adopted will be modified or invalidated. The continuing health care reform initiatives efforts of the government, insurance companies, managed care organizations and other payers of health care services to contain or reduce costs of health care may adversely affect the demand for any product candidates for which we may 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 revenues and achieve or maintain profitability; and the level of taxes that we are required to pay.

Our relationships with healthcare providers and physicians and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the U.S. and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Arrangements with third-party payors and customers can expose pharmaceutical manufacturers to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act (“FCA”), which may constrain the business or financial arrangements and relationships through which such companies sell, market and distribute pharmaceutical products. In particular, the research of our product candidates, as well as the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information received in the course of patient recruitment for clinical trials. The applicable federal, state and foreign healthcare laws and regulations laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, 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 a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal FCA. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;

- the federal civil and criminal false claims laws and civil monetary penalty laws, including the FCA, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by Medicare, Medicaid, or other federal healthcare programs, knowingly making, using or causing to be made or using a false record or statement material to a

false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The government may deem manufacturers to have "caused" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;

- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and their respective implementing regulations, which impose, among other things, requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their respective business associates, independent contractors that perform services for covered entities that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;

- the federal Physician Payments Sunshine Act, created under the Patient Protection and Affordable Care Act ("ACA"), and its implementing regulations, which require some manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services ("HHS") information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and may be broader in scope than their federal equivalents; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

In addition to the above, on November 20, 2020, the Office of Inspector General ("OIG") finalized further modifications to the federal Anti-Kickback Statute. Under the final rules, OIG added safe harbor protections under the Anti-Kickback Statute for certain coordinated care and value-based arrangements among clinicians, providers, and others. The final rule (with some exceptions) became effective January 19, 2021. We continue to evaluate what effect, if any, these rules will have on our business.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time and resource consuming and can divert a company's attention from the business.

In addition, there has been a trend of increased state regulation of payments made to physicians for marketing. Some states mandate implementation of corporate compliance programs, along with the tracking and reporting of gifts, compensation, and other remuneration to physicians.

It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Any action for violation of these laws, even if successfully defended, could cause a pharmaceutical manufacturer to incur significant legal expenses and divert management's attention from the operation of the business. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way.

Failure to comply with health and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business.

We, our CROs, and any potential collaborators may be subject to federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the U.S., numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), 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 CROs and collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA, as amended by HITECH. Depending on the facts and circumstances, we could be subject to civil, criminal, and administrative penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with these laws and regulations could result in government enforcement actions (which could include civil, criminal and administrative penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects, employees and other individuals about whom we or our potential collaborators obtain personal information, as well as the providers who

share this information with us, may limit our ability to collect, use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, 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.

We conduct our TOPAZ Phase 2 clinical trial of apitegromab in the European Economic Area ("EEA"), may conduct future clinical trials in the EEA and therefore may be subject to additional privacy laws. The General Data Protection Regulation, (EU) 2016/679 ("GDPR") became effective on May 25, 2018, and deals with the collection, use, storage, disclosure, transfer or other processing of personal data and on the free movement of such data. The GDPR imposes a broad range of strict requirements on companies subject to the GDPR, including requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside the EEA, including to the U.S., providing details to those individuals regarding the processing of their personal information, keeping personal information secure, having data processing agreements with third parties who process personal information, responding to individuals' requests to exercise their rights in respect of their personal information, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments, and record-keeping. The GDPR increases substantially the penalties to which we could be subject in the event of any non-compliance, including fines of up to 10,000,000 Euros or up to 2% of our total worldwide annual turnover for certain comparatively minor offenses, or up to 20,000,000 Euros or up to 4% of our total worldwide annual turnover for more serious offenses. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR includes restrictions on cross-border data transfers.

The GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. Given the new law, we face uncertainty as to the exact interpretation of the new requirements and we may be unsuccessful in implementing all measures required by data protection authorities or courts in interpretation of the new law. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. Following the U.K.'s withdrawal from the EU on January 31, 2020 and the end of the transitional arrangements agreed between the U.K. and EU as of January 1, 2021, the GDPR has been incorporated into U.K. domestic law by virtue of section 3 of the European Union (Withdrawal) Act 2018 and amended by the Data Protection, Privacy and Electronic Communications (Amendments etc.) (EU Exit) Regulations 2019. U.K.-based organizations doing business in the EU will need to continue to comply with the GDPR. Further, there is uncertainty with regard to how data transfers to and from the U.K. will be regulated.

EU Member States have adopted implementing national laws to implement the GDPR which may partially deviate from the GDPR and the competent authorities in the EU Member States may interpret GDPR obligations slightly differently from country to country, so that we do not expect to operate in a uniform legal landscape in the EU. Also, as it relates to processing and transfer of genetic data, the GDPR specifically allows national laws to impose additional and more specific requirements or restrictions, and European laws have historically differed quite substantially in this field, leading to additional uncertainty.

In the conduct of our current or future clinical trials in the EEA, we must also ensure that we maintain adequate safeguards to enable the transfer of personal data outside of the EEA, in particular to the U.S., in compliance with European data protection laws. We expect that we will continue to face uncertainty as to whether our efforts to comply with our obligations under European privacy laws will be sufficient. If we are investigated by a European data protection authority, we may face fines and other penalties. Any such investigation or charges by European data protection authorities could have a negative effect on our existing business and on our ability to attract and retain new clients or pharmaceutical partners. We may also experience hesitancy, reluctance, or refusal by European or multi-national clients or pharmaceutical partners to continue to use our products and solutions due to the potential risk exposure as a result of the current (and, in particular, future) data protection obligations imposed on them by certain data protection authorities in interpretation of current law, including the GDPR. Such clients or pharmaceutical partners may also view any alternative approaches to compliance as being too costly, too burdensome, too legally uncertain, or otherwise

objectionable and therefore decide not to do business with us. Any of the foregoing could materially harm our business, prospects, financial condition and results of operations.

In addition, California recently enacted the California Consumer Policy Act ("CCPA"), which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide certain disclosures to consumers about its data collection, use and sharing practices, and to provide affected California residents with ways to opt-out of certain sales or transfers of personal information. The CCPA went into effect on January 1, 2020, and the California Attorney General has commenced bringing enforcement actions against violators as of July 1, 2020. While there are currently exceptions for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact our business activities. We continue to monitor the impact the CCPA may have on our business activities.

Additional laws and regulations governing international operations, including certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, could negatively impact or restrict our operations.

If we further expand our operations outside of the U.S., we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act **"(**FCPA") prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the U.S. to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the U.S., or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the U.S., it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the U.S., which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our research and development activities involve the use of biological and hazardous materials and produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for

handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological waste or hazardous waste insurance coverage, workers compensation or property and casualty and general liability insurance policies that include coverage for damages and fines arising from biological or hazardous waste exposure or contamination.

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

We face an inherent risk of product liability as a result of testing apitegromab, SRK-181 and any of our future product candidates in clinical trials and will face an even greater risk if we commercialize any products, if approved. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical trials, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- inability to bring a product candidate to the market;
- decreased demand for our products;
- injury to our reputation;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- diversion of management's time and our resources;
- substantial monetary awards to trial participants;
- 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, if approved; and
- decline in our share price.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with collaborators. We may be unable to obtain, or may obtain on unfavorable terms, additional clinical trial insurance in amounts adequate to cover any liabilities from any of our clinical trials. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

Inadequate funding for the FDA, the SEC and other government agencies, including from government shut downs, or other disruptions to these agencies' operations, could prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

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

Since March 2020 when foreign and domestic inspections of facilities were largely placed on hold, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. The FDA has developed a rating system to assist in determining when and where it is safest to conduct domestic inspections. In April 2021, the FDA issued guidance for the industry formally announcing plans to employ remote interactive evaluations, using risk management methods, to meet user fee commitments and goal dates. Additionally, as of March 18, 2021, the FDA noted it is continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic in line with its user fee performance goals and conducting mission critical domestic and foreign inspections to ensure compliance of manufacturing facilities with FDA quality standards. However, the FDA may not be able to continue its current pace and approval timelines could be extended, including where a pre-approval inspection or an inspection of clinical sites is required and due to the COVID-19 pandemic and travel restrictions the FDA is unable to complete such required inspections during the review period. Should the FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be appropriate, the agency has stated that it generally intends to issue a complete response letter. In 2020, several companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Additionally, regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. If a prolonged government shutdown or other disruption occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Future shutdowns or other disruptions could also affect other government agencies such as the SEC, which may also impact our business by delaying review of our public filings, to the extent such review is necessary, and our ability to access the public markets.

Our current operations are concentrated in one location, and we or the third parties upon whom we depend may experience business interruptions and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster, including earthquakes, outbreak of disease or other natural disasters.

Our office and laboratory facilities are located in Cambridge, Massachusetts. Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities, the facilities at any clinical trial site, or the manufacturing facilities of our third-party contract manufacturers, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of apitegromab, SRK-181 and future product candidates or interruption of our business operations. If a natural disaster, outbreak of disease, power outage or other event occurred that prevented us from using

all or a significant portion of our headquarters, that damaged critical infrastructure, such as our research facilities or the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. For example, the COVID-19 pandemic has already resulted in extended shutdowns of certain businesses and has had ripple effects to businesses around the world. This virus continues to spread globally and, as of March 2021, has spread to a number of countries, including the U.S. where cases continue to rise in certain states. The outbreak and government measures taken in response have had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. In response to the spread of the COVID-19 coronavirus, most of our employees are continuing their work remotely outside of our offices. As a result of the COVID-19 pandemic, our ability to identify and enroll patients in current and future clinical trials may become more difficult and costly and data readouts from our clinical trials may be delayed or adversely impacted. The full extent to which the COVID-19 pandemic impacts our business or operations will depend on future developments, which are highly uncertain and cannot be accurately predicted, including new information which may emerge concerning the severity of the COVID-19 coronavirus and the actions to contain the COVID-19 coronavirus or treat its impact, among others. Global health concerns, such as the COVID-19 pandemic, could also result in social, economic, and labor instability in the countries in which we or the third parties with whom we engage operate.

The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our third-party contract manufacturers, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption may have a material and adverse effect on our business, financial condition, results of operations and prospects.

Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, if approved, which could make it difficult for us to sell any product candidates profitably.

The success of our product candidates, apitegromab, SRK-181 and future product candidates, if approved, depends on the availability of coverage and adequate reimbursement from third-party payors. We cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, apitegromab, SRK-181 or future product candidates or assure that coverage and reimbursement will be available for any product that we may develop.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance.

Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor’s determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

In the U.S., no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products on a payor by payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of product candidates. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates. There is significant uncertainty related to insurance coverage and reimbursement of newly approved products. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

Payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. Additional state and federal healthcare reform measures are expected to be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for certain pharmaceutical products or additional pricing pressures.

Moreover, increasing efforts by governmental and third-party payors in the U.S. and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. There has been increasing legislative and enforcement interest in the U.S. with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, cost containment initiatives and additional legislative changes. Further, due to the COVID-19 pandemic, millions of individuals have lost or will be losing employer-based insurance coverage, which may adversely affect our ability to commercialize our products.

In addition, coverage and reimbursement for products can differ significantly from payor to payor. One payor’s decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service, or will provide coverage at an adequate reimbursement rate. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS, an agency within the U.S. Department of Health and Human Services. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree.

Payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. In order to obtain and maintain coverage and reimbursement for any product, we may need to conduct expensive evidence generation studies in order to demonstrate the medical necessity and cost-effectiveness of such a product, in addition to the costs required to obtain regulatory approvals. If payors do not consider a product to be cost-effective compared to current standards of care, they may not cover the product as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to cover its costs or make a profit. While any proposed measures will require authorization through additional legislation to become effective, Congress and the Biden administration have each indicated that they will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

EU drug marketing and reimbursement regulations may materially affect our ability to market and receive coverage for our products in the European member states.

We intend to seek approval to market our product candidates in both the U.S. and in selected foreign jurisdictions. If we receive approval in one or more foreign jurisdictions for apitegromab, SRK-181 or future product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the EU, the pricing of medicinal products is subject to governmental control and other market regulations which could put pressure on the pricing and usage of our product candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after receiving marketing approval of a product candidate. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidates and may be affected by existing and future health care reform measures.

Much like the federal Anti-Kickback Statute prohibition in the U.S., the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the EU. The provision of benefits or advantages to physicians is governed by the national anti-inducement, advertising and anti-bribery laws of EU Member States. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain EU Member States must be disclosed publicly. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

In addition, in most foreign countries, including several EU Member States, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Reference pricing used by various EU member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. In some countries, we may be required to conduct a clinical study or other studies that compare the cost-effectiveness of any of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the EU do not follow price structures of the U.S. and generally prices tend to be significantly lower. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales by us or our strategic partners and the potential profitability of any of our product candidates in those countries would be negatively affected.

The failure to maintain the Gilead Collaboration Agreement, or the failure of Gilead to perform its obligations under or our failure to achieve certain milestones under the Gilead Collaboration Agreement could negatively impact our business, financial condition, results of operations and prospects.

On December 19, 2018, we entered into the Gilead Collaboration Agreement, to discover and develop specific inhibitors of TGFβ activation focused on the treatment of fibrotic diseases. Under the collaboration, Gilead has exclusive options to license worldwide rights to product candidates that emerge from three of our TGFβ programs (each a "Gilead Program"). Pursuant to the Gilead Collaboration Agreement, we are responsible for antibody discovery and preclinical research through product candidate nomination, after which, upon exercising the option for a Gilead Program, Gilead will be responsible for the Gilead Program's preclinical and clinical development and commercialization. In consideration of the foregoing, we received $80 million in upfront payments, comprised of $50 million in cash and a $30

million equity investment in us. In addition, in January 2020, we received a one-time milestone payment of $25.0 million for the successful demonstration of efficacy in preclinical in vivo proof-of-concept studies and will be eligible to receive up to an additional $1,425 million in potential payments aggregated across all three Gilead Programs, based on the successful achievement of certain research, development, regulatory and commercialization milestones. We would also receive high single-digit to low double-digit tiered royalties on sales of potential future products originating from the collaboration. We cannot guarantee the outcome of our efforts to achieve such milestones, and, even if we achieve such milestones, we cannot directly control Gilead's performance of its obligations under the agreement or the amount and timing of resources that Gilead will dedicate to these efforts, and accordingly, we may not receive any additional milestone or royalty payments that are contingent upon our or Gilead's achievements.

We are subject to a number of other risks associated with our collaboration with Gilead, including:

- If we are able to identify program antibodies and present Gilead with development candidate nominations, Gilead may not exercise its option to such program or we and Gilead could disagree as to future development plans, and Gilead may delay, fail to commence, or stop future preclinical and clinical development and commercialization.

- If Gilead exercised one or more options, following such exercise, Gilead will have sole responsibility for the development and commercialization of the product candidates from such program in the applicable field. Gilead will have the sole discretion to determine and direct its efforts and resources, including the ability to discontinue all efforts and resources it applies to the development and, if approval is received, commercialization and marketing of the product candidates covered by the applicable program. Gilead may not be effective in receiving approvals for the product candidates developed from the programs or in marketing, or arranging for necessary supply, manufacturing or distribution relationships for, any approved products. Furthermore, Gilead may change its strategic focus or pursue alternative technologies in a manner that results in reduced, delayed or no revenue to us. Gilead has a variety of marketed products and product candidates under collaboration with other companies, including some of our competitors, and its own corporate objectives may not be consistent with our best interests. If Gilead fails to develop, receive regulatory approval for or ultimately commercialize any product candidate from the programs covered by the Gilead Collaboration Agreement, or if Gilead terminates our collaboration, our business, financial condition, results of operations and prospects would be harmed.

- There may be disputes between Gilead and us, including disagreements regarding the Gilead Collaboration Agreement, that may result in the delay of development programs, creation of uncertainty as to ownership of, control of, or access to intellectual property rights, litigation or arbitration proceedings, distraction of our management from other business activities, and our incurrence of substantial expenses. Any disagreements could result in failure to achieve developmental, regulatory and sales objectives that would have otherwise resulted in milestone or royalty payments to us or the delay or termination of any future development or commercialization of a Gilead Program.

The Gilead Collaboration Agreement is also subject to early termination, including through Gilead's right under certain circumstances to terminate upon advance notice to us. If the Gilead Collaboration Agreement is terminated early, we may not be able to find another collaborator for the further development and commercialization of the three Gilead Programs covered by the Gilead Collaboration Agreement on acceptable terms, or at all, and we may be unable to pursue continued development and commercialization of such programs on our own.

We may not be successful in our efforts to discover antibodies or identify potential product candidates under the Gilead Collaboration Agreement or Gilead may not elect to exercise its option to license our product candidates.

A key element of our strategy under the Gilead Collaboration Agreement is to use our proprietary technology to identify program antibodies that meet the development criteria for such Gilead Program. Our antibody discovery process may not be successful in identifying antibodies that meet the development criteria for a Gilead Program under the Gilead Collaboration Agreement or that we believe qualify as product candidates. Even if we identify and nominate a product candidate for any Gilead Program, Gilead may not choose to exercise its option for the Gilead Program or may not be successful in developing or commercializing such product candidate. If Gilead elected not to exercise an option, we

would have incurred significant discovery and research expenses but may not be eligible to receive future milestone or royalty payments related to such program. Further development of a product candidate may also be discontinued by Gilead if the product candidate is shown to have harmful side effects or if other characteristics are observed that indicate the product candidate may be unlikely to receive marking approval or achieve market acceptance. If Gilead decides not to move forward with a product candidate, that could negatively affect our business, including our reputation, and could hinder our ability to enter into future collaborations.

We may seek to enter into collaborations in the future with other third parties, including for apitegromab, SRK-181 or potential product candidates. If we are unable to enter into such collaborations, or if these collaborations are not successful, our business could be adversely affected.

A part of our strategy is to evaluate and, as deemed appropriate, enter into additional collaborations or partnerships in the future when strategically attractive, including potentially with major biotechnology or pharmaceutical companies. We have limited capabilities for product development and do not yet have any capability for commercialization. Accordingly, we may enter into collaborations with other companies to provide us with important technologies, capabilities and funding for our programs and underlying technology.

Any future collaboration we enter into may pose a number of risks, including the following:

- collaborators may have significant discretion or decision-making authority in determining the efforts and resources that they will apply to the collaboration or that we are required to apply to the collaboration;
- collaborators may not perform their obligations as expected or in a manner satisfactory to us;
- we may commit to certain preclinical or clinical development or commercialization efforts as part of the collaboration that we are unable to meet or our collaborators may not be satisfied with our preclinical or clinical development or commercialization efforts;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs or license arrangements based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as a strategic transaction that may divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products and product candidates if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- collaborators may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;
- collaborators with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;

- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or terminations of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;

- 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 potential litigation;

- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;

- if a collaborator of ours is involved in a business combination, the collaborator might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us; and

- collaborations may be terminated by the collaborator, and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

If our collaborations do not result in the successful discovery, 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 such collaboration. All of the risks relating to product development, regulatory approval and commercialization described in this Annual Report on Form 10-K also apply to the activities of our therapeutic collaborators.

Additionally, if one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the biotechnology or pharmaceutical industry, including within the business and financial communities, could be adversely affected.

We face significant competition in seeking appropriate partners for our product candidates, and the negotiation process is time-consuming and complex. In order for us to successfully partner our product candidates, potential partners must view these product candidates as economically valuable in markets they determine to be attractive in light of the terms that we are seeking and other available products for licensing by other companies. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms, or at all. If we fail to enter into collaborations or do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates, bring them to market and generate revenue from sales of drugs or continue to develop our technology, and our business may be materially and adversely affected. Even if we are successful in our efforts to establish new strategic collaborations, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such strategic collaborations if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing. Any delay in entering into new strategic collaboration agreements related to our product candidates could delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market.

Risks Related to Our Intellectual Property

Our success depends in part on our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.

Our commercial success will depend in large part on obtaining and maintaining patent, trademark and trade secret protection of our proprietary technologies and our product candidates, their respective components, formulations, combination therapies, methods used to manufacture them and methods of treatment, as well as successfully defending these patents against third-party challenges. Our ability to stop unauthorized third parties from making, using, selling, offering to sell or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents that cover these activities. If we are unable to secure and maintain patent protection for any product or technology we develop, or if the scope of the patent protection secured is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to commercialize any product candidates we may develop may be adversely affected.

The patenting process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, we may not pursue or obtain patent protection in all relevant markets. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and are reliant on our licensors or licensees.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates or uses thereof in the U.S. and/or in other foreign countries. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property and/or prevent others from designing around our claims. If the breadth or strength of protection provided by the patent applications we hold with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced.

We cannot be certain that we are the first to invent the inventions covered by pending patent applications and, if we are not, we may be subject to priority disputes. We may be required to disclaim part or all of the term of certain patents or all of the term of certain patent applications. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. No assurance can be given that if challenged, our patents would be declared by a court to be valid or enforceable or that even if found valid and enforceable, a competitor’s technology or product would be found by a court to infringe our patents. We may analyze patents or patent applications of our competitors that we believe are relevant to our activities, and consider that we are free to operate in relation to our product candidates, but our competitors may achieve issued claims, including in patents we consider to be unrelated, which block our efforts or may potentially result in our product candidates or our activities infringing such claims. The possibility exists that others will develop products which have the same effect as our products on an independent basis which do not infringe our patents or other intellectual property rights, or will design around the claims of patents that we have had issued that cover our products.

In addition, periodic maintenance fees on any issued patent are due to be paid to the U.S. patent office (“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 provisions during the patent application process and following the issuance of a patent. 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, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. Moreover, complications due to the COVID-19 pandemic may result in inadvertent lapse due to, for example, unexpected closures of the USPTO or foreign patent offices, delays in delivery of notifications relating to deadlines, or failure to timely and/or properly obtain signatures on necessary documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make or use compounds or cells that are similar to the biological compositions of our product candidates but that are not covered by the claims of our patents;
- the active biological ingredients in our current product candidates will eventually become commercially available in biosimilar drug products, and no patent protection may be available with regard to formulation or method of use;
- we or our licensors, as the case may be, may fail to meet our obligations to the U.S. government in regards to any in-licensed patents and patent applications funded by U.S. government grants, leading to the loss of patent rights;
- we or our licensors, as the case may be, might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that our pending patent applications will not result in issued patents;
- it is possible that there are prior public disclosures that could invalidate our or our licensors' patents, as the case may be, or parts of our or their patents;
- it is possible that others may circumvent our owned or in-licensed patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours;
- the laws of foreign countries may not protect our or our licensors', as the case may be, proprietary rights to the same extent as the laws of the U.S.;
- the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not cover our product candidates;
- our owned or in-licensed issued patents may not provide us with any competitive advantages, may be narrowed in scope, or be held invalid or unenforceable as a result of legal challenges by third parties;
- the inventors of our owned or in-licensed patents or patent applications may become involved with competitors, develop products or processes which design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors;
- it is possible that our owned or in-licensed patents or patent applications omit individual(s) that should be listed as inventor(s) or include individual(s) that should not be listed as inventor(s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable;
- we have engaged in scientific collaborations in the past, and will continue to do so in the future. Such collaborators may develop adjacent or competing products to ours that are outside the scope of our patents;

- we may not develop additional proprietary technologies for which we can obtain patent protection;
- it is possible that product candidates or diagnostic tests we develop may be covered by third parties' patents or other exclusive rights; and/or
- the patents of others may have an adverse effect on our business.

Our current owned patents and co-owned patents covering our proprietary technologies and our product candidates are expected to expire beginning in 2034 (owned) and November 2033 (co-owned), respectively, without taking into account any possible patent term adjustments or extensions. Our earliest patents may expire before, or soon after, our first product achieves marketing approval in the U.S. or foreign jurisdictions. Upon the expiration of our current patents, we may lose the right to exclude others from practicing these inventions. The expiration of these patents could also have a material adverse effect on our business, results of operations, financial condition and prospects. We own and co-own pending patent applications covering our proprietary technologies or our product candidates that if issued as patents are expected to expire from November 2033 through 2042 without taking into account any possible patent term adjustments or extensions. However, we cannot be assured that the USPTO or relevant foreign patent offices will grant any of these patent applications.

We depend on intellectual property licensed from third parties. Failure to comply with our obligations under any of these licenses or termination of any of these licenses could result in the loss of significant rights, which would harm our business.

We are dependent on patents, know-how and proprietary technology, including intellectual property rights licensed from others. We may be a party to license agreements pursuant to which we in-license key patents and patent applications for our product candidates. These licenses impose various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, our licensors may have the right to terminate the license. Any termination of licenses by third parties could result in our loss of significant intellectual property rights and could harm our ability to commercialize our product candidates.

We may have limited control over the maintenance and prosecution of these in-licensed patents and patent applications, activities or any other intellectual property that may be related to our in-licensed intellectual property. For example, we cannot be certain that such activities by these licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. 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 that is licensed to us. It is possible that the licensors' infringement proceeding or defense activities may be less vigorous than had we conducted them ourselves.

Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

We may not be successful in obtaining or maintaining necessary rights to develop any future product candidates on acceptable terms.

Because our programs may involve additional product candidates that may require the use of additional proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights.

Our product candidates may also require specific formulations to work effectively and efficiently, and these rights may be held by others. We may develop products containing our compounds and pre-existing pharmaceutical compounds. We may be required by the FDA or comparable foreign regulatory authorities to provide a companion diagnostic test or tests with our product candidates. These diagnostic test or tests may be covered by intellectual property rights 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 or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

Additionally, we sometimes collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business and financial condition could suffer.

The licensing or acquisition of third-party intellectual property rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire.

Changes in patent law in the U.S. and in ex U.S. jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

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 and legal complexity, and is therefore costly, time-consuming and inherently uncertain.

In addition, recent or future patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. Under the enacted Leahy-Smith America Invents Act (the "America Invents Act"), enacted in 2013, the U.S. moved from a "first to invent" to a "first to file" system. Under a "first to file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. The America Invents Act includes a number of other significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted, redefine prior art and establish a new post-grant review system. The effects of these changes are currently unclear as the USPTO only recently developed new regulations and procedures in connection with the America Invents Act, and many of the substantive changes to patent law, including the "first to file" provisions, only became effective in March 2013. In addition, the courts have yet

to address many of these provisions and the applicability of the act and new regulations on specific patents discussed herein have not been determined and would need to be reviewed. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Recent U.S. Supreme Court rulings have also narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. As a consequence, issued patents may be found to contain invalid claims according to the newly revised eligibility and validity standards. Additionally, some of our owned or in-licensed patents may be subject to challenge and subsequent invalidation or significant narrowing of claim scope in proceedings before the USPTO, or during litigation, under the revised criteria which could also make it more difficult to obtain 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 would 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 Amgen Inc. v. Sanofi, the Federal Circuit held that a well characterized antigen is insufficient to satisfy the written description requirement of certain claims directed to a genus of antibodies that are solely defined by function. While the validity of a subset of patents at issue was subsequently upheld by a district court jury, uncertainty remains as to the legal question pertaining to the written description requirement under 35 USC §112 as it relates to functional antibodies. In the case of Assoc. for Molecular Pathology v. Myriad Genetics, Inc., the U.S. Supreme Court held that certain claims to DNA molecules are not patentable. We cannot predict how these decisions or any future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents. Similarly, any adverse changes in the patent laws of other jurisdictions could have a material adverse effect on our business and financial condition.

Third-party claims of intellectual property infringement may prevent or delay our product discovery and development efforts.

Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation, inter partes review, post-grant review, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates and/or proprietary technologies infringe their intellectual property rights. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

If a third-party claims that we infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;
- substantial damages for infringement, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third-party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;

- a court prohibiting us from developing, manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third-party licenses its product rights to us, which it is not required to do;
- if a license is available from a third-party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our products; and
- redesigning our product candidates or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Third parties may assert that we are employing their proprietary technology without authorization. Generally, conducting clinical trials and other development activities in the U.S. is protected under the Safe Harbor exemption as set forth in 35 U.S.C. § 271. If and when apitegromab, SRK-181 or another one of our product candidates is approved by the FDA, that certain third-party may then seek to enforce its patent by filing a patent infringement lawsuit against us. While we are not aware of any claims of such a patent that could otherwise materially adversely affect commercialization of our product candidates, we may be incorrect in this belief, or we may not be able to prove it in a litigation. In this regard, patents issued in the U.S. by law enjoy a presumption of validity that can be rebutted only with evidence that is "clear and convincing," a heightened standard of proof. There may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, constructs or molecules used in or formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms, or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future 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. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, and/or pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly.

We may also choose to challenge the patentability of claims in a third-party's U.S. patent by requesting that the USPTO review the patent claims in an ex-parte re-exam, inter partes review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge the grant of a third-party's patent in opposition proceedings in the European Patent Office ("EPO") or other foreign patent office. The costs of these opposition proceedings could be substantial, and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, the EPO or other patent office, then we may be exposed to litigation by a third-party alleging that the patent may be infringed by our product candidates or proprietary technologies.

We may incur substantial costs as a result of litigation or other proceedings relating to our patents or the patents of our licensors, and we may be unable to protect our rights to our products and technology.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims against a third party(ies), which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. There is also the risk that, even if the validity of our patents or the patents of our licensors is upheld, the court will refuse to stop the third-party on the ground that such third-party's activities do not infringe our owned or in-licensed patents. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

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

In some situations, we or our licensor, may not be able to detect infringement against our owned or in-licensed patents, as the case may be, which may be especially difficult for manufacturing processes or formulation patents. Even if we or our licensors detect infringement by a third-party of our owned or in-licensed patents, we or our licensors, as the case may be, may choose not to pursue litigation against or settlement with the third-party. If we, or our licensors, later sue such third-party for patent infringement, the third-party may have certain legal defenses available to it, which otherwise would not be available except for the delay between when the infringement was first detected and when the suit was brought. Such legal defenses may make it impossible for us or our licensors to enforce our owned or in-licensed patents, as the case may be, against such third-party.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court or the USPTO.

If we or one of our licensing partners initiate legal proceedings against a third-party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third-party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the U.S. or abroad, even outside the context of litigation. Such mechanisms include inter parties review, ex parte re-examination, post-grant review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings are expensive and could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, or if we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and product candidates.

In addition, because some patent applications in the U.S. may be maintained in secrecy until the patents are issued, because patent applications in PCT member jurisdictions are typically not published until 18 months after the earliest filing, and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our owned and in-licensed issued patents or our pending applications, or that we or, if applicable, a licensor were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering our products, compositions, methods of use, or technology similar to ours. Any such patent application may have priority over our owned and in-licensed patent applications or patents, which could require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to those owned by or in-licensed to us, we or, in the case of in-licensed technology, the licensor may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the U.S. If we or one of our licensors is a party to an interference proceeding involving a U.S. patent application on inventions owned by or in-licensed to us, we may incur substantial costs, divert management's time and expend other resources, even if we are successful.

For applications filed under pre-AIA, interference proceedings declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation or interference proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the U.S.

We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world.

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

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceutical products and/or methods of medical treatment, which could make it difficult for us to stop the infringement of our patents or marketing of competing products against third parties in violation of our proprietary rights generally. The initiation of proceedings by third parties to challenge the scope or validity of our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Patent terms may result in inadequate protection for our product candidates, and we may be unable to obtain patent term extensions and data exclusivity for our product candidates, resulting in material harm to our business.

Patents have a limited lifespan. In the U.S., if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions such as patent term adjustments and/or extensions, may be available, but the life of a patent, and the protection it affords, is limited.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, 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 Action of 1984, also known as the Hatch Waxman Amendments. The Hatch Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. The patent term restoration period is generally one-half of the time between the effective date of the IND or the date of patent grant (whichever is later) and the date of submission of the BLA, plus the time between the date of submission of the BLA and the date of FDA approval of the product. The patent holder must apply for restoration within 60 days of approval. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. We may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request.

Given the amount of time required for the development, testing and regulatory review of new product candidates, the patents protecting our product candidates might expire before or shortly after such candidates are commercialized. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours, which could materially harm our business, financial condition, results of operations, and prospects.

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

In addition to patent protection, we rely heavily upon know-how and trade secret protection, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants and third parties, to protect our confidential and proprietary information, especially where we do not believe patent protection is appropriate or obtainable. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third-party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed.

In addition, courts outside the U.S. are sometimes less willing to protect trade secrets. If we choose to go to court to stop a third-party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology.

Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality

agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties. We have also adopted policies and conduct training that provides guidance on our expectations, and our advice for best practices, in protecting our trade secrets.

Third parties may assert that our employees or consultants have wrongfully used, disclosed, or misappropriated their confidential information or trade secrets.

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at universities or other biopharmaceutical or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, and although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding 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 intellectual property related proceedings could adversely affect our ability to compete in the marketplace.

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 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 or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. 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.

Risks Related to Our Financial Condition and Capital Requirements

We have incurred net losses in every year since our inception and anticipate that we will continue to incur net losses in the future.

We are a biopharmaceutical company formed in 2012 and our operations to date have been focused on research and development of monoclonal antibodies that selectively inhibit activation of growth factors for therapeutic effect. We have not yet demonstrated the ability to progress any of our product candidates through clinical trials, we have no products approved for commercial sale and we have not generated any revenue from product sales to date. We continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception. For the three months ended March 31, 2021 and 2020, we reported a net loss of $27.7 million and $17.1 million, respectively. As of March 31, 2021, we had an accumulated deficit of $272.0 million. We expect to continue to incur significant losses for the foreseeable future, and

we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates, apitegromab and SRK-181, and any future product candidates.

To become and remain profitable, we or any current or potential future collaborators must develop and eventually commercialize products with significant market potential and favorable pricing. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials, receiving marketing approval for product candidates, manufacturing, marketing and selling products for which we may receive marketing approval and satisfying any post-marketing requirements. We may never succeed in any or all of these activities and, even if we do, we may never generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable could decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations.

Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We will require additional capital to fund our operations and if we fail to obtain necessary capital, we will not be able to complete the development and commercialization of apitegromab, SRK-181 and any future product candidates.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts of cash to conduct further research and development, including clinical trials for apitegromab and SRK-181 and preclinical studies and clinical trials for any future product candidates, to seek regulatory approvals for our product candidates and to launch and commercialize any products for which we receive regulatory approval. As of March 31, 2021, we had approximately $314.7 million in cash, cash equivalents and marketable securities. Based on our current operating plan, we believe that our existing cash, cash equivalents and marketable securities as of March 31, 2021, will be sufficient to fund our operating expenses and capital expenditure requirements into 2023. However, our future capital requirements and the period for which our existing resources will support our operations may vary significantly from what we expect, and we will in any event require additional capital in order to complete clinical development of any of our current programs. Our monthly spending levels will vary based on new and ongoing development and corporate activities. Because the length of time and activities associated with development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and commercialization activities. Additionally, any program setbacks or delays due to changes in federal or state laws or clinical site or clinical vendor policies as a result of the COVID-19 pandemic could impact our programs and increase our expenditures. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, completion, costs and results of clinical trials for apitegromab and SRK-181 and preclinical studies and clinical trials for any future product candidates;
- the clinical development plans we establish for our product candidates;
- the number and characteristics of product candidates that we identify and develop;
- the terms of any collaboration, strategic alliance, or licensing agreements we are currently party to or may choose to enter into in the future;
- the impact of the COVID-19 pandemic on the initiation or completion of preclinical studies or clinical trials and the supply of our product candidates;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, the EMA, and other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;

- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us or our product candidates;
- the effect of competing technological and market developments;
- the cost and timing of developing research cell lines and development and completion of commercial scale outsourced manufacturing activities; and
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own.

We do not have any committed external source of funds or other support for our development efforts other than pursuant to our Gilead Collaboration Agreement and our license agreement with Janssen, which payments we may not receive in full or at all, and we cannot be certain that additional funding will be available on acceptable terms, or at all. Even if we receive the maximum payments under the Gilead Collaboration Agreement or license agreement with Janssen, the payments may not meet our current or future funding requirements. Until we can generate sufficient product or royalty revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest will be diluted. In addition, any debt financing may subject us to fixed payment obligations and covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. We also could be required to seek collaborators for apitegromab, SRK-181 or any future product candidate at an earlier stage than otherwise would be desirable or relinquish our rights to product candidates or technologies that we otherwise would seek to develop or commercialize ourselves. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of apitegromab, SRK-181 or one or more of our future product candidates or other research and development initiatives. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

Changes in tax law could adversely affect our business and financial condition.

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock.

Our ability to use our net operating loss carryforwards and certain tax credit carryforwards may be subject to limitation.

As of December 31, 2020, we had net operating loss carryforwards for federal and state income tax purposes of $168.4 million and $170.1 million, respectively, which begin to expire in 2032, except for our post 2017 federal net operating loss carryforwards of $117.9 million which do not expire. As of December 31, 2020, we also had available tax credit carryforwards for federal and state income tax purposes of $15.4 million and $2.6 million, respectively, which begin to expire in 2034 and 2021, respectively. Additionally, for taxable years beginning after December 31, 2020 the deductibility of such federal net operating losses is limited to 80% of our taxable income in any future taxable year. Under Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), changes in our ownership may limit the amount of our net operating loss carryforwards and tax credit carryforwards that could be utilized annually to offset

our future taxable income, if any. This limitation would generally apply in the event of a cumulative change in ownership of our company of more than 50% within a three-year period. Any such limitation may significantly reduce our ability to utilize our net operating loss carryforwards and tax credit carryforwards before they expire. Private placements and other transactions that have occurred since our inception, as well as our initial public offering ("IPO"), may trigger such an ownership change pursuant to Section 382 of the Code. Any such limitation, whether as the result of our IPO, prior private placements, sales of our common stock by our existing stockholders or additional sales of our common stock by us, could have a material adverse effect on our results of operations in future years.

Risks Related to Our Common Stock

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

Similar to the trading prices of the common stock of other biopharmaceutical companies, the trading price of our common stock is subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Quarterly Report, these factors include:

- announcements of significant acquisitions, strategic collaborations or partnerships, joint ventures or capital commitments by us, our collaborators or our competitors;
- actual or anticipated variations in quarterly operating results or our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- changes in accounting practices; and
- significant lawsuits, including patent or stockholder litigation.

In addition, the stock market in general, and the market for 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, including as a result of the COVID-19 pandemic. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. 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.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Furthermore, our ability to pay cash dividends is currently restricted by the terms of our credit facility with Oxford and SVB, and future debt or other financing arrangements may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Any return to stockholders will therefore be limited to the appreciation of their stock.

Our Board members, management, and their affiliates, own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of March 31, 2021, our executive officers, directors and their affiliates beneficially hold, in the aggregate, approximately 17.6% of our outstanding voting stock. These stockholders, acting together, are able to significantly influence all matters requiring stockholder approval. For example, these stockholders are able to significantly influence 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.

We are an "emerging growth company" and a "smaller reporting company," and we cannot be certain if the reduced reporting requirements applicable to emerging growth and smaller reporting companies will make our common stock less attractive to investors.

We are an Emerging Growth Company ("EGC"), as defined in the Jumpstart Our Business Startups Act (the "JOBS Act"), enacted in April 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended ("Sarbanes-Oxley Act");
- reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements;
- exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved;
- not being required to comply 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; and
- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure.

We will remain an emerging growth company until the earlier of (1) December 31, 2023 (2) the last day of the fiscal year in which we have total annual gross revenue of at least $1.07 billion or (3) the last day of the fiscal year in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed $700 million as of the last business date of our most recently completed second fiscal quarter, and (4) the date on which we have issued more than $1 billion in non-convertible debt during the prior three-year period. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price 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 have irrevocably elected not to avail ourselves of delayed adoption of new or revised accounting standards and, therefore, we will be subject to the same requirements to adopt new or revised accounting standards as other public companies that are not emerging growth companies.

We are also a "smaller reporting company" as defined in the Exchange Act, and have elected to take advantage of certain of the scaled disclosures available to smaller reporting companies.

We expect to continue to incur increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act and rules subsequently implemented by the SEC and Nasdaq have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. These rules and regulations have significantly increased our legal and financial compliance costs and we anticipate that these activities will become more time-consuming and costly over time.

Pursuant to Section 404, we are required to furnish a report by our management on our internal control over financial reporting, and, once we are no longer an EGC or a "smaller reporting company", we will be required to furnish an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we are engaged in a process to document

and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction to the trading price of our common stock in the financial markets due to a loss of confidence in the reliability of our financial statements.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

We are required to disclose changes made in our internal controls and procedures on a quarterly basis and our management will be required to assess the effectiveness of these controls annually. However, for as long as we are an EGC or a “smaller reporting company”, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. We could be an EGC for up to five years following the completion of our IPO and will qualify as a “smaller reporting company” if the market value of our common stock held by non-affiliates is below $250 million (or $700 million if our annual revenue is less than $100 million) as of June 30 in any given year. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management’s assessment might not. Undetected material weaknesses in our internal controls over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation.

We have broad discretion in the use of our existing cash, cash equivalents and marketable securities and may not use them effectively.

Our management has broad discretion in the application of our existing cash, cash equivalents and marketable securities. Because of the number and variability of factors that will determine our use of our existing cash and cash equivalents, their ultimate use may vary substantially from their currently intended use. Our management might not apply our existing cash and cash equivalents in ways that ultimately increase the value of your investment. The failure by our management to apply these funds effectively could harm our business.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;

- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer, or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue convertible preferred stock on terms determined by the board of directors without stockholder approval and which convertible preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

If securities or industry analysts publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

Our amended and restated bylaws contain certain exclusive forum provisions requiring that substantially all disputes between us and our stockholders be resolved in certain judicial forums, 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 bylaws provide that the Court of Chancery of the State of Delaware will be the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our certificate of incorporation or our bylaws, any action to interpret, apply, enforce, or determine the validity of our certificate of incorporation or bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine. In addition, our amended and restated bylaws contain a provision by virtue of which, unless we consent in writing to the selection of an alternative forum, the U.S. District Court for the District of Massachusetts will be the exclusive forum for any complaint asserting a cause of action arising under the Securities Act. In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the foregoing provisions. We have chosen the U.S. District Court for the District of Massachusetts as the exclusive forum for such causes of action because our principal executive offices are located in Cambridge, Massachusetts. Some companies that have adopted similar federal district court forum selection provisions are currently subject to a suit in the Court of Chancery of the State of Delaware brought by stockholders who

assert that the federal district court forum selection provision is not enforceable. While the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are “facially valid” under Delaware law, there is uncertainty as to whether other courts will enforce our federal forum selection provision, and we may incur additional costs of litigation should such enforceability be challenged. If the federal forum selection provision is otherwise found inapplicable to, or unenforceable in respect of, one or more of the specified actions or proceedings, we may incur additional costs, which could have an adverse effect on our business, financial condition or results of operations. We recognize that the federal district court forum selection clause may impose additional litigation costs on stockholders who assert the provision is not enforceable and may impose more general additional litigation costs in pursuing any such claims, particularly if the stockholders do not reside in or near the Commonwealth of Massachusetts. Additionally, the choice of forum provision may limit a stockholder’s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

Item 2. Unregistered Sales of Equity Securities

Recent Sales of Unregistered Securities

Not applicable.

Issuer Purchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

None.

Item 6. Exhibits

EXHIBIT INDEX

Exhibit Number	Description	Incorporated by Reference to: Form	File No.	Exhibit No.	Filing Date
3.1	Amended and Restated Certificate of Incorporation of the Registrant	S-1/A	333-224493	3.2	May 8, 2018
3.2	Amendment to Amended and Restated Certificate of Incorporation of the Registrant	S-1/A	333-224493	3.1.1	May 14, 2018
3.3	Amended and Restated By-laws of the Registrant	S-1/A	333-224493	3.4	May 8, 2018
4.1	Investors' Rights Agreement among the Registrant and certain of its stockholders, dated December 22, 2017	S-1	333-224493	4.1	April 27, 2018
4.2	Specimen Stock Certificate evidencing shares of common stock	S-1/A	333-224493	4.2	May 14, 2018
4.3	Amended and Restated Warrant to Purchase Stock, by and between Silicon Valley Bank and the Registrant, dated December 22, 2017	S-1	333-224493	4.3	April 27, 2018
31.1*	Certification of Principal Executive Officer Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934				
31.2*	Certification of Principal Financial Officer Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934				
32.1**	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
101.INS	XBRL Instance Document				
101.SCH	XBRL Taxonomy Extension Schema Document				
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.*)				

* Filed herewith

** Furnished herewith

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.

SCHOLAR ROCK HOLDING CORPORATION

Date: May 13, 2021	By:	/s/ Stuart A. Kingsley
		Stuart A. Kingsley President and Chief Executive Officer (Principal Executive Officer)
Date: May 13, 2021	By:	/s/ Edward H. Myles
		Edward H. Myles Chief Financial Officer and Head of Business Operations (Principal Financial Officer)

Exhibit 31.1

Certifications

I, Stuart A. Kingsley, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Scholar Rock Holding Corporation;

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

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

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

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

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

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

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

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

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

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

Date: May 13, 2021

/s/ Stuart A. Kingsley
Stuart A. Kingsley
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certifications

I, Edward H. Myles, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Scholar Rock Holding Corporation;

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

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

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

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

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

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

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

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

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

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

Date: May 13, 2021

/s/ Edward H. Myles
Edward H. Myles
Chief Financial Officer and Head of Business Operations
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO

18 U.S.C. SECTION 1350

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Scholar Rock Holding Corporation (the "Company") for the period ended March 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to his or her knowledge, that:

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

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

This certification is being provided pursuant to 18 U.S.C. 1350 and is not to be deemed a part of the Report, nor is it to be deemed to be "filed" for any purpose whatsoever.

Date: May 13, 2021

/s/ Stuart A. Kingsley
Stuart A. Kingsley
President and Chief Executive Officer

Date: May 13, 2021

/s/ Edward H. Myles
Edward H. Myles
Chief Financial Officer and Head of Business Operations