UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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: 001-40522

Monte Rosa Therapeutics, Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**84-3766197**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
645 Summer Street, Suite 102 Boston, Massachusetts	**02210**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 949-2643

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

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

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

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

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

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

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

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

As of November 9, 2021, the registrant had 46,505,914 shares of common stock, $0.0001 per share, outstanding.

Summary of the material risks associated with our business

Our business is subject to numerous material and other risks and uncertainties that you should be aware of in evaluating our business. These risks are described more fully in Part II, "Item 1A—Risk Factors," and include, but are not limited to, the following:

- We are a biotechnology company with a limited operating history and have not generated any revenue to date from drug sales, and may never become profitable
- We have incurred significant operating losses since our inception and anticipate that we will incur continued losses for the foreseeable future
- We are very early in our development efforts. All of our programs are still in the preclinical stages of drug discovery. If we are unable to commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed
- Our approach to the discovery and development of product candidates based on our QuEEN platform is novel, which makes it difficult to predict the time, cost of development and likelihood of successfully developing any products
- We may not be successful in our efforts to identify or discover additional product candidates or we may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success
- Even if we receive marketing authorization for our product candidates, we will be subject to extensive 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 we are unable to obtain and maintain patent and other intellectual property protection for our technology and product candidates or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and drugs may be impaired, and we may not be able to compete effectively in our market
- We own patent applications related to our QuEEN platform, our CDK2 program, our NEK7 program, and our GSPT1 program, including GSPT1-directed MGDs, biomarkers related to these compounds, and methods of reading through nonsense mutations. We currently do not own any issued patents. Further, patent prosecution related to our pending patent applications is in the early stages and, as such, no patent examiner has yet fully scrutinized the merits of any of our pending patent applications
- Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel
- Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses
- We have identified material weaknesses in our internal control over financial reporting. If we are unable to successfully remediate these material weaknesses in our internal control over financial reporting, it could have an adverse effect on our company
- Our executive officers, directors, principal stockholders and their affiliates own a significant percentage of our stock and are able to exercise significant influence over our company, which will limit your ability to influence corporate matters and could delay or prevent a change in corporate control

Special note regarding forward-looking statements

This Quarterly Report on Form 10-Q, or Quarterly Report, contains forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, or the or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. 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. These statements are not guarantees of future results or performance and involve substantial risks and uncertainties. Forward-looking statements in this Quarterly Report include, but are not limited to, statements about:

- the initiation, timing, progress, results, cost and success of our current and future research and development programs and preclinical studies, including our expectations for our GSPT1-directed MGD molecules;
- the initiation, timing, progress, results, cost and success of our future clinical trials, including statements regarding the period during which the results of the clinical trials will become available;
- our ability to continue to develop our proprietary protein degradation platform called QuEEN and to expand our proteomics and translational medicine capabilities;
- the potential advantages of our platform technology and product candidates;
- the extent to which our scientific approach and platform technology may target proteins that have been considered undruggable or inadequately drugged;
- our plans to submit an IND application to the FDA for our lead GSPT1-directed MGD product candidate and future product candidates;
- the potential benefits of strategic collaborations and our ability to enter into strategic collaborations with third parties who have the expertise to enable us to further develop our biological targets, product candidates and platform technology;
- our ability to obtain and maintain regulatory approval of our product candidates;
- our ability to manufacture, including through third-party manufacturers, our product candidates for preclinical use, future clinical trials and commercial use, if approved;
- our ability to commercialize our product candidates, including our ability to establish sales, marketing and distribution capabilities;
- the rate and degree of market acceptance of our product candidates;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- our ability to establish and maintain intellectual property rights covering our current and future product candidates and technologies;
- the implementation of our business model and strategic plans for our business, product candidates, and technology;
- estimates of our future expenses, revenues, capital requirements, and our needs for additional financing;
- our ability to obtain funding for our operations necessary to complete further development and commercialization of our product candidates;
- our financial performance;
- developments in laws and regulations in the United States and foreign countries;
- the success of competing therapies that are or may become available;
- our ability to attract and retain key scientific or management personnel;
- the impact of the COVID-19 pandemic on our business and operations; and
- other risks and uncertainties, including those listed under the section entitled “Risk factors.”

Any forward-looking statements in this Quarterly Report reflect our current views with respect to future events and with respect to our future financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those described under Part II, Item 1A, "Risk Factors" and elsewhere in this Quarterly Report. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

All of our forward-looking statements are as of the date of this Quarterly Report only. In each case, actual results may differ materially from such forward-looking information. We can give no assurance that such expectations or forward-looking statements will prove to be correct. An occurrence of or any material adverse change in one or more of the risk factors or risks and uncertainties referred to in this Quarterly Report or included in our other public disclosures or our other periodic reports or other documents or filings filed with or furnished to the Securities and Exchange Commission, or the SEC, could materially and adversely affect our business, prospects, financial condition and results of operations. Except as required by law, we do not undertake or plan to update or revise any such forward-looking statements to reflect actual results, changes in plans, assumptions, estimates or projections or other circumstances affecting such forward-looking statements occurring after the date of this Quarterly Report, even if such results, changes or circumstances make it clear that any forward-looking information will not be realized. Any public statements or disclosures by us following this Quarterly Report that modify or impact any of the forward-looking statements contained in this Quarterly Report will be deemed to modify or supersede such statements in this Quarterly 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.

Table of Contents

We have applied for various trademarks that we use in connection with the operation of our business. All other trade names, trademarks and service marks of other companies appearing in this Quarterly Report are the property of their respective holders. Solely for convenience, the trademarks and trade names in this Quarterly Report may be referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend to use or display other companies' trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

From time to time, we may use our website, our Facebook page at Facebook.com/Monte-Rosa-Therapeutics, our Twitter at @MonteRosaTx and on our LinkedIn account at linkedin.com/company/monte-rosa-therapeutics to distribute material information. Our financial and other material information is routinely posted to and accessible on the Investors section of our website, available at www.monterosatx.com. Investors are encouraged to review the Investor Relations section of our website because we may post material information on that site that is not otherwise disseminated by us. Information that is contained in and can be accessed through our website, our Facebook page, our Twitter posts and our LinkedIn posts are not incorporated into, and does not form a part of, this Quarterly Report.

Part I — Financial Information

Item 1. Financial Statements

Monte Rosa Therapeutics, Inc.
Condensed consolidated balance sheets

(in thousands, except share and per share amounts) (unaudited)	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 367,034	$ 41,699
Prepaid expenses and other current assets	3,485	1,892
Total current assets	370,519	43,591
Property and equipment, net	11,801	4,623
Restricted cash	1,729	1,164
Total assets	$ 384,049	$ 49,378
Liabilities, convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 3,530	$ 7,066
Accrued expenses and other current liabilities	9,213	2,529
Preferred stock tranche obligations	—	19,680
Total current liabilities	12,743	29,275
Defined benefit plan liability	2,001	1,067
Total liabilities	14,744	30,342
Commitments and contingencies		
Convertible preferred stock, $0.0001 par value; 10,000,000 shares authorized, an no shares issued and outstanding as of September 30, 2021; and 77,631,514 shares authorized and 53,631,514 shares issued and outstanding as of December 31, 2020	—	67,764
Stockholders' equity (deficit)		
Common stock, $0.0001 par value; 500,000,000 shares authorized, 46,780,847 shares issued and 46,483,918 shares outstanding as of September 30, 2021; and 97,500,000 shares authorized, 2,180,803 shares issued and 1,685,534 shares outstanding as of December 31, 2020	5	1
Additional paid-in capital	469,845	404
Accumulated other comprehensive loss	(1,950)	(1,056)
Accumulated deficit	(98,595)	(48,077)
Total stockholders' equity (deficit)	369,305	(48,728)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 384,049	$ 49,378

See accompanying notes to the condensed combined and consolidated financial statements.

Monte Rosa Therapeutics, Inc.
Condensed combined and consolidated statements of operations and comprehensive loss

(in thousands, except share and per share amounts) (unaudited)	Three months ended September 30, 2021	Three months ended September 30, 2020	Nine months ended September 30, 2021	Nine months ended September 30, 2020
Operating expenses:				
Research and development	$ 15,115	$ 5,472	$ 39,025	$ 14,142
General and administrative	4,753	914	10,470	1,932
Total operating expenses	19,868	6,386	49,495	16,074
Loss from operations	(19,868)	(6,386)	(49,495)	(16,074)
Other income (expense):				
Interest income, net	13	2	33	—
Foreign currency exchange gain (loss), net	18	(174)	(96)	(149)
Changes in fair value of preferred stock tranche obligations, net	—	—	(960)	—
Total other (expense) income	31	(172)	(1,023)	(149)
Net loss	$ (19,837)	$ (6,558)	$ (50,518)	$ (16,223)
Provision for pension benefit obligation	(535)	—	(894)	—
Comprehensive loss	$ (20,372)	$ (6,558)	$ (51,412)	$ (16,223)
Reconciliation of net loss to net loss attributable to common stockholders				
Net loss	$ (19,837)	$ (6,558)	$ (50,518)	$ (16,223)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.43)	$ (4.29)	$ (2.85)	$ (11.01)
Weighted-average number of shares outstanding used in computing net loss per common share—basic and diluted	45,987,866	1,529,881	17,751,410	1,474,045

See accompanying notes to the condensed combined and consolidated financial statements.

Monte Rosa Therapeutics, Inc.
Condensed combined and consolidated statements of convertible preferred stock and stockholders’ equity (deficit)

	Convertible preferred stock		Common stock					
(in thousands, except share amounts) (unaudited)	Shares	Amount	Shares	Amount	Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total Stockholders’ equity (deficit)
Balance—January 1, 2021	53,631,514	$ 67,764	1,685,534	$ 1	$ 404	$ (1,056)	$ (48,077)	$ (48,728)
Restricted common stock vesting	—	—	36,565	—	—	—	—	—
Issuance of Series B convertible preferred stock, net of issuance costs of $69	24,000,000	68,571	—	—	—	—	—	—
Issuance of Series C convertible preferred stock, net of issuance costs of $163	32,054,521	94,837	—	—	—	—	—	—
Provision for pension benefit obligation	—	—	—	—	—	136	—	136
Stock-based compensation expense	—	—	—	—	252	—	—	252
Net Loss	—	—	—	—	—	—	(12,276)	(12,276)
Balance—March 31, 2021	109,686,035	$ 231,172	1,722,099	$ 1	656	$ (920)	$ (60,353)	$ (60,616)
Restricted common stock vesting	—	—	36,580	—	—	—	—	—
Exercise of common stock options	—	—	76,950	—	128	—	—	128
Conversion of convertible preferred stock into common stock	(109,686,035)	(231,172)	31,068,102	2	231,170	—	—	231,172
Issuance of common stock in connection with initial public offering, net of issuance costs of $18.5 million	—	—	11,700,000	1	203,874	—	—	203,875
Provision for pension benefit obligation	—	—	—	—	—	(495)	—	(495)
Stock-based compensation expense	—	—	—	—	1,019	—	—	1,019
Net Loss	—	—	—	—	—	—	(18,405)	(18,405)
Balance—June 30, 2021	—	$ —	44,603,731	$ 4	436,847	$ (1,415)	$ (78,758)	$ 356,678
Restricted common stock vesting	—	—	125,187	—	—	—	—	—
Issuance of common stock in connection with initial public offering, net of issuance costs of $2.3 million	—	—	1,755,000	1	30,925	—	—	30,926
Provision for pension benefit obligation	—	—	—	—	—	(535)	—	(535)
Stock-based compensation expense	—	—	—	—	2,073	—	—	2,073
Net Loss	—	—	—	—	—	—	(19,837)	(19,837)
Balance—September 30, 2021	—	$ —	46,483,918	$ 5	469,845	$ (1,950)	$ (98,595)	$ 369,305
Balance—January 1, 2020	19,250,000	18,950	1,416,230	50	—	—	(12,198)	(12,148)
Stock-based compensation expense	—	—	—	—	11	—	—	11
Net Loss	—	—	—	—	—	—	(4,302)	(4,302)
Balance—March 31, 2020	19,250,000	$ 18,950	1,416,230	$ 50	11	$ —	$ (16,500)	$ (16,439)
Restricted common stock vesting	—	—	72,247	—	—	—	—	—
Change in par value of common stock due to the Contribution and Exchange agreement	—	—	—	(50)	50	—	—	—
Conversion of convertible note and accrued interest to Series A convertible preferred stock	754,280	754	—	—	—	—	—	—
Issuance of Series A-2 convertible preferred stock, net of issuance costs of $178	9,627,234	12,322	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	97	—	—	97
Net Loss	—	—	—	—	—	—	(5,364)	(5,364)
Balance—June 30, 2020	29,631,514	$ 32,026	1,488,477	$ —	158	$ —	$ (21,864)	$ (21,706)
Restricted common stock vesting	—	—	118,824	—	—	—	—	—
Issuance of Series B convertible preferred stock, net of issuance costs of $262 and discount on allocation of proceeds to preferred stock tranche obligation of $12,000	24,000,000	35,738	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	45	—	—	45
Net Loss	—	—	—	—	—	—	(6,558)	(6,558)
Balance—September 30, 2020	53,631,514	$ 67,764	1,607,301	$ —	203	$ —	$ (28,422)	$ (28,219)

See accompanying notes to the condensed combined and consolidated financial statements.

Monte Rosa Therapeutics, Inc.
Condensed combined and consolidated statements of cash flows

(in thousands) (unaudited)	Nine months ended September 30, 2021	2020
Cash flows from operating activities:		
Net loss	$ (50,518)	$ (16,223)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation expense	3,344	153
Depreciation	1,323	314
Changes in fair value of preferred stock tranche obligations	960	—
Loss on disposal of property and equipment	13	—
Changes in operating assets and liabilities		
Prepaid expenses and other current assets	(1,593)	(676)
Accounts payable	(5,446)	1,506
Accrued expenses and other current liabilities	6,726	447
Net cash used in operating activities	$ (45,191)	$ (14,479)
Cash flows from investing activities:		
Purchases of property and equipment	(6,673)	(2,203)
Proceeds from sale of property and equipment	67	—
Net cash used in investing activities	$ (6,606)	$ (2,203)
Cash flows from financing activities:		
Proceeds from issuance of convertible preferred stock	143,000	60,500
Payment of convertible preferred stock issuance costs	(231)	(430)
Proceeds from initial public offering, net of underwriting discount of $17.9 million	237,750	—
Payment of initial public offering issuance costs	(2,950)	—
Proceeds from exercise of employee stock options	128	—
Net cash provided by financing activities	$ 377,697	$ 60,070
Net increase in cash, cash equivalents and restricted cash	$ 325,900	$ 43,388
Cash, cash equivalents and restricted cash—beginning of period	42,863	9,245
Cash, cash equivalents and restricted cash—end of period	$ 368,763	$ 52,633
Reconciliation of cash, cash equivalents and restricted cash		
Cash and cash equivalents	$ 367,034	$ 51,673
Restricted cash	1,729	960
Total cash, cash equivalents and restricted cash	$ 368,763	$ 52,633
Supplemental disclosure of noncash items		
Conversion of convertible preferred stock into common stock	$ 231,172	$ —
Settlement of preferred stock tranche obligation	$ 20,640	$ —
Conversion of convertible note payable and accrued interest into Series A convertible preferred stock	$ —	$ 754
Purchases of property and equipment in accounts payable	$ 1,909	$ 478

See accompanying notes to the condensed combined and consolidated financial statements.

Monte Rosa Therapeutics, Inc.
Notes to the condensed combined and consolidated financial statements
(unaudited)

1. Description of business, contribution and exchange, and liquidity

Business

Monte Rosa Therapeutics, Inc. is a biotechnology company developing a portfolio of novel small molecule precision medicines that employ the body's natural mechanisms to selectively degrade therapeutically-relevant proteins. As used in these condensed combined and consolidated financial statements, unless the context otherwise requires, references to the Company or Monte Rosa refer to Monte Rosa Therapeutics, Inc. and its wholly owned subsidiaries Monte Rosa Therapeutics AG and Monte Rosa Therapeutics Securities Corp. The Company was incorporated in Delaware in November 2019 and is headquartered in Boston, Massachusetts with research operations in both Boston and Basel, Switzerland.

Contribution and exchange

Monte Rosa Therapeutics AG, a Swiss operating company, was incorporated in April 2018. Monte Rosa Therapeutics, Inc. was incorporated in November 2019. In 2020, Monte Rosa Therapeutics, Inc. and Monte Rosa Therapeutics AG, entities under common control since the incorporation of Monte Rosa Therapeutics, Inc., consummated a contribution and exchange agreement, or the Contribution and Exchange, whereby Monte Rosa Therapeutics, Inc. acquired the net assets and shareholdings of Monte Rosa Therapeutics AG via a one-for-one exchange of equity between Monte Rosa Therapeutics, Inc. and the shareholders of Monte Rosa Therapeutics AG in a common control reorganization. Accordingly, the historical financial information has been retrospectively adjusted to include the historical results and financial position of Monte Rosa Therapeutics, Inc. combined with Monte Rosa Therapeutics AG's historical results and financial position, after the elimination of all intercompany accounts and transactions.

Initial Public Offering

In June 2021 the Company completed its initial public offering, or IPO, and issued an aggregate of 11,700,000 shares of common stock at a price to the public of $19.00 per share. The Company received aggregate net proceeds from the IPO of $203.9 million, after deducting underwriting discounts and commissions of $15.6 million and offering costs of $2.9 million. In connection with the IPO, the Company granted the underwriters a 30-day option to purchase an additional 1,755,000 shares. In July 2021, the underwriters exercised the option in full and the Company issued 1,755,000 shares of common stock for aggregate net proceeds of $31.0 million after deducting underwriter discounts and commissions of $2.3 million.

Immediately prior to consummation of the IPO, all outstanding shares of the Company's Series A, Series A-2, Series B and Series C convertible preferred stock were converted into 31,068,102 shares of common stock. The Company's common stock began trading on the Nasdaq Global Select Market on June 24, 2021 under the symbol “GLUE”.

Liquidity considerations

Since inception, the Company has devoted substantially all its efforts to business planning, research and development, recruiting management and technical staff, and raising capital and has financed its operations primarily through the issuance of convertible preferred shares.

The Company's continued discovery and development of its product candidates will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities. Even if product development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

As of September 30, 2021, the Company had an accumulated deficit of $98.6 million. The Company has incurred losses and negative cash flows from operations since inception, including net losses of $50.5 million and $16.2 million for the nine months ended September, 2021 and 2020, respectively. The Company expects that its operating losses and negative cash flows will continue for the foreseeable future as the Company continues to develop its product candidates. The Company currently expects that its cash and cash equivalents of $367.0 million as of September 30, 2021 will be sufficient to fund operating expenses and capital requirements for at least 12 months from the date the condensed combined and consolidated financial statements are issued. However, additional funding will be necessary to fund future discovery research, pre-clinical and clinical activities. The Company will seek additional funding through public financings, debt financings, collaboration agreements, strategic alliances and licensing arrangements. Although it has been successful in raising capital in the past, there is no assurance that the Company will be successful in obtaining such additional financing on terms acceptable to it, if at all, and the Company may not be able to enter into collaborations or other arrangements. If the Company is unable to obtain funding, it could be forced to delay, reduce or eliminate its research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect the Company's business prospects, even the ability to continue operations.

Coronavirus pandemic

The coronavirus, or COVID-19, pandemic has spread worldwide, and has caused many governments to implement measures to slow the spread of the outbreak through quarantines, travel restrictions, heightened border scrutiny and other measures. The outbreak and government measures taken in response have also had a significant impact, both directly and indirectly, 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. The future progression of the outbreak and its effects on the Company's business and operations are uncertain. To date, our operations have not been significantly impacted by the COVID-19 pandemic.

The actual and perceived impact of the COVID-19 pandemic is changing daily, and its ultimate effect on the Company cannot be predicted. As a result, there can be no assurance that the Company will not experience additional negative impacts associated with COVID-19, which could be significant. The COVID-19 pandemic may negatively impact the Company's business, financial condition and results of operations causing interruptions or delays in the Company's programs and services.

2. Summary of significant accounting policies

There have been no changes to the significant accounting policies as disclosed in Note 2 to the Company's annual combined and consolidated financial statements for the year ended December 31, 2020 included in the final prospectus for the Company's IPO filed pursuant to Rule 424(b)(4) under the Securities Act with the Securities and Exchange Commission, or SEC on June 25, 2021.

Unaudited Financial Information

The Company's condensed combined and consolidated financial statements included herein have been prepared in conformity with accounting principles generally accepted in the United States of America, or GAAP, and pursuant to the rules and regulations of the SEC. In the Company's opinion, the information furnished reflects all adjustments, all of which are of a normal and recurring nature, necessary for a fair presentation of the financial position and results of operations 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.

Recently issued accounting pronouncements

The Company has elected to use the extended transition period for complying with new or revised accounting standards as available under the Jumpstart Our Business Startups Act (JOBS Act).

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, as amended, or ASU 2016-02, with guidance regarding the accounting for and disclosure of leases. The update requires lessees to recognize the liabilities related all leases, including operating leases, with a term greater than 12 months on the balance sheet. This update also requires lessees and lessors to disclose key information about their leasing transactions. This standard is effective for annual reporting periods beginning after December 15, 2021, and interim periods within annual periods beginning after December 15, 2022. Early adoption is permitted. The Company is currently assessing the potential impact of adopting ASU 2016-02 on its financial statements and financial statement disclosures.

In June 2016, the FASB issued Accounting Standards Update No. 2016-13, *Financial Instruments-Credit Losses: Measurement of Credit Losses on Financial Instruments*. ASU 2016-13 requires measurement and recognition of expected credit losses for financial assets. In April 2019, the FASB issued clarification to ASU 2016-13 within ASU 2019-04, *Codification Improvements to Topic 326, Financial Instruments-Credit Losses, Topic 815, Derivatives and Hedging*, *and Topic 825, Financial Instruments*, or ASU 2016-13. The guidance is effective for fiscal years beginning after December 15, 2022. The Company is currently assessing the potential impact of adopting ASU 2016-13 on its financial statements and financial statement disclosures.

In December 2019, the FASB issued ASU 2019-12, *Simplifying the Accounting for Income Taxes*, or ASU 2019-12. ASU 2019-12 eliminates certain exceptions related to the approach for intra-period tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. It also clarifies and simplifies other aspects of the accounting for income taxes. This guidance is effective for fiscal years beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022. Early adoption is permitted. The Company is currently assessing the impact adoption of ASU 2019-12 will have on the financial statements and disclosures.

In August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging Contracts in Entity s Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*. ASU 2020-06 will simplify the accounting for convertible instruments by reducing the number of accounting models for convertible debt instruments and convertible preferred stock. Limiting the accounting models results in fewer embedded conversion features being separately recognized from the host contract as compared with current GAAP. Convertible instruments that continue to be subject to separation models are (i) those with embedded conversion features that are not clearly and closely related to the host contract, that meet the definition of a derivative, and that do not qualify for a scope exception from derivative accounting and (ii) convertible debt instruments issued with substantial premiums for which the premiums are recorded as paid-in capital. ASU 2020-06 also amends the guidance for the derivatives scope exception for contracts in an entity's own equity to reduce form-over-substance-based accounting conclusions. ASU 2020-06 will be effective for the Company beginning after December 15, 2023. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. The Company is currently assessing the impact adoption of ASU 2020-06 will have on its financial statements and disclosures.

3. Fair value measurements

The following tables present information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values (in thousands):

	As of September 30, 2021			
	Level 1	Level 2	Level 3	Total
Current assets				
Money market funds	$ 144,845	$ —	$ —	$ 144,845
Pension plan assets(1)	—	3,017	—	3,017
Total assets measured at fair value	$ 144,845	$ 3,017	$ —	$ 147,862

	As of December 31, 2020			
	Level 1	Level 2	Level 3	Total
Current assets				
Money market funds	$ 38,712	$ —	$ —	$ 38,712
Pension plan assets(1)	—	1,217	—	1,217
Total assets measured at fair value	$ 38,712	$ 1,217	$ —	$ 39,929
Current liabilities				
Preferred stock tranche obligation	$ —	$ —	$ 19,680	$ 19,680
Total liabilities measured at fair value	$ —	$ —	$ 19,680	$ 19,680

(1) The fair value of pension plan assets has been determined as the surrender value of the portfolio of active insured members held within the Swiss Life Collective BVG Foundation collective investment fund.

Money market funds are highly liquid investments and are actively traded. The pricing information on the Company's money market funds are based on quoted prices in active markets for identical securities. This approach results in the classification of these securities as Level 1 of the fair value hierarchy.

The Company's Series B Preferred Stock Tranche Obligation is measured at fair value using a Black-Scholes option pricing valuation methodology. The fair value of Series B Preferred Stock Tranche Obligation includes inputs not observable in the market and thus represents a Level 3 measurement. The option pricing valuation methodology utilized requires inputs based on certain subjective assumptions, including (i) expected stock price volatility, (ii) calculation of an expected term, (iii) a risk-free interest rate, and (iv) expected dividends. The assumptions utilized to value the Series B Preferred Stock Tranche Obligation as of December 31, 2020 were (i) expected stock price volatility of 93%; (ii) remaining term of 1.7 years; (iii) a risk-free interest rate of 0.12%; and (iv) an expectation of no dividends. The assumptions utilized to value the Series B Preferred Stock Tranche Obligation just prior to settlement were (i) expected stock price volatility of 26%; (ii) remaining term 0.003 years; (iii) a risk-free rate of 0.04%; and (iv) an expectation of no dividends. The Series B Preferred Stock Tranche Obligation was extinguished in February 2021 upon the issuance of the Series B Preferred Stock. Immediately prior to the issuance of the Series B Preferred Stock in February 2021, the Company adjusted the carrying value of the liability to its estimated fair value of $20.6 million.

The following table provides a reconciliation of assets and liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) (in thousands):

	Nine months ended September 30, 2021
Balance at beginning of period	$ 19,680
Change in fair value	960
Settlement of Preferred Stock Tranche Obligation	(20,640)
Balance at end of period	$ —

There were no transfers among Level 1, Level 2 or Level 3 categories in the nine months ended September 30, 2021 and 2020.

4. Property and Equipment, net

Property and equipment, net, consist of the following (in thousands):

	September 30, 2021	December 31, 2020
Laboratory equipment	$ 12,064	$ 5,205
Furniture and fixtures	277	—
Computer hardware and software	328	27
Leasehold improvements	1,028	—
Total property and equipment, at cost	$ 13,697	$ 5,232
Less: accumulated depreciation	(1,896)	(609)
Property and equipment, net	$ 11,801	$ 4,623

Depreciation expense for the nine months ended September 30, 2021 and 2020, was $1,323,000 and $314,000, respectively.

5. Convertible preferred stock

In April 2020, the Company authorized the sale of up to 9,635,000 shares of its Series A-2 Preferred at a price of $1.2984 per share and issued 9,627,234 shares of Series A-2 Preferred to a single investor for aggregate gross proceeds of $12.4 million.

In September 2020, the Company authorized the sale of up to 48,000,000 shares of its Series B Preferred at a price of $2.00 per share, or Series B Financing. In an initial closing in September 2020, the Company issued 24,000,000 shares of Series B Preferred to several new and existing investors for aggregate gross proceeds of $48.0 million. The Series B Financing further allowed certain purchasers of Series B Preferred the option, or the Series B Preferred Stock Tranche Obligation, to purchase up to an additional 24,000,000 shares of Series B Preferred at a price per share of $2.00, which occurred in February 2021 as described below.

The Company concluded that the Preferred Stock Tranche Obligation met the definition of a freestanding financial instrument, as it is legally detachable and separately exercisable from the Series B Preferred. Therefore, the Company allocated the proceeds received from the issuance of shares under the Series B Preferred Stock Purchase Agreement between the Preferred Stock Tranche Obligation and the Series B Preferred. The fair value of the Preferred Stock Tranche Obligation of $12.0 million on issuance was allocated from the $48.0 million proceeds of the Series B Preferred financing and is classified as a current liability on the combined and consolidated balance sheet as of December 31, 2020 as the Series B Preferred would become redeemable upon a Deemed Liquidation Event, the occurrence of which is not within the Company’s control.

In February 2021, the Company issued 24,000,000 shares of Series B Preferred pursuant to the Preferred Stock Tranche Obligation for aggregate gross proceeds of $48.0 million less issuance costs of $69,000.

In March 2021, the Company authorized the sale of up to 32,054,521 shares of its Series C Preferred Stock at a price of $2.9637 per share, and issued the authorized shares of Series C Preferred to several new and existing investors for aggregate gross proceeds of $95.0 million less issuance costs of $163,000.

Immediately prior to consummation of the IPO, all outstanding shares of the Company’s Series A, Series A-2, Series B and Series C convertible preferred stock were converted into 31,068,102 shares of common stock.

6. Common stock

The Company’s board of directors approved a one-for-3.5305 reverse stock split of its issued and outstanding common stock and stock options and a proportional adjustment to the existing conversion ratios for the Company’s preferred stock effective as of June 17, 2021. Accordingly, all share and per share amounts for all periods presented in the accompanying financial statements and notes thereto have been retroactively adjusted, where applicable, to reflect the reverse stock split

The Company had 500,000,000 shares of common stock authorized, of which 46,780,847 shares were issued and 46,483,918 shares were outstanding at September 30, 2021.

The holders of common stock are entitled to dividends when and if declared by the board of directors. The board of directors has not declared any dividends and the Company has not paid any dividends.

The holders of common stock are entitled to one vote per share on all matters to be voted upon by the stockholders.

The Company has issued restricted stock to founders, employees and consultants, and expense for this restricted stock is recognized on a straight-line basis (see Note 7). The restricted stock generally vests monthly over 4 years.

As of September 30, 2021 and December 31, 2020, the Company has reserved the following shares of common stock for potential conversion of outstanding Convertible Preferred Stock, the vesting of restricted stock and exercise of stock options:

	September 30, 2021	December 31, 2020
Convertible preferred stock	—	53,631,514
Options to purchase common stock	5,566,421	2,205,380
Unvested restricted common stock	296,929	495,278
	5,863,350	56,332,172

7. Stock-based compensation

2020 Stock incentive plan

The Company’s 2020 Stock Option and Grant Plan, or the 2020 Plan, provided for the Company to grant stock options, restricted stock and other stock awards, to employees, non-employee directors, and consultants. Upon the effectiveness of the 2021 Plan (as defined below), no further issuances will be made under the 2020 Plan.

2021 Stock incentive plan

The Company’s 2021 Stock Option and Incentive Plan, or the 2021 Plan, was approved by the Company’s board of directors on May 28, 2021, and the Company’s stockholders on June 17, 2021, and became effective on the date immediately prior to the date on which the registration statement for the Company’s IPO was declared effective. The 2021 Plan provides for the grant of incentive stock options, non-qualified stock options, stock appreciation rights, restricted stock units, restricted stock awards, unrestricted stock awards, cash-based awards and dividend equivalent rights to the Company’s officers, employees, directors and consultants. The number of shares initially reserved for issuance under the 2021 Plan is 4,903,145, which will be automatically increased on January 1, 2022 and each January 1 thereafter by 5% of the outstanding number of shares of the Company’s common stock on the immediately preceding December 31 or such lesser number of shares as determined by the Company’s compensation, nomination and corporate governance committee.

2021 Employee stock purchase plan

The Company's 2021 Employee Stock Purchase Plan, or the 2021 ESPP, was approved by the Company's board of directors on May 28, 2021, and the Company's stockholders on June 17, 2021, and became effective on the date immediately prior to the date on which the registration statement for the Company's IPO was declared effective. A total of 439,849 shares of the Company's common stock were initially reserved for issuance under the 2021 ESPP, which will be automatically increased on January 1, 2022 and each January 1 thereafter through January 1, 2031, by the least of (i) 439,849 shares of the Company's common stock, (ii) 1% of the outstanding number of shares of the Company's common stock on the immediately preceding December 31, 2020 or (iii) such lesser number of shares of the Company's common stock as determined by the plan administrator of the 2021 ESPP.

Stock option activity

The following summarizes stock option activity:

	Number of options		Weighted average exercise price	Weighted average remaining contractual term (years)		Aggregate intrinsic value (in thousands)
Outstanding—December 31, 2020	2,205,380	$	2.05	9.9	$	312
Granted	3,812,300		10.14			
Exercised	(76,950)		1.66			1,619
Forfeited	(374,309)		2.19			
Outstanding—September 30, 2021	5,566,421	$	7.58	9.4	$	82,185
Vested or expected to vest—September 30, 2021	5,566,421	$	7.58	9.4	$	82,185
Exercisable—September 30, 2021	239,924	$	4.11	9.1	$	4,360

The aggregate intrinsic value of options granted is calculated as the difference between the exercise price of the options and the estimated fair value of the Company's common stock.

Restricted stock award activity

The following summarizes restricted stock activity:

	Number of shares		Weighted average grant date fair value
Unvested as of December 31, 2020	495,278	$	1.02
Vested	(198,349)	$	1.19
Unvested as of September 30, 2021	296,929	$	0.90

The aggregate fair value of restricted stock that vested during the nine months ended September 30, 2021 and 2020 was $236,000 and $131,000, respectively. The weighted average grant date fair value of restricted stock that vested during the nine months ended September 30, 2021 was $1.19.

Stock-based compensation expense

Stock-based compensation expense is classified as follows (in thousands):

	Nine months ended September 30,	
	2021	2020
Research and development	$ 1,559	$ 74
General and administrative	1,785	79
Total stock-based compensation expense	$ 3,344	$ 153

As of September 30, 2021, total unrecognized stock–based compensation cost related to unvested stock options and restricted stock awards was $26.1 million and $251,000, respectively. The Company expects to recognize this remaining cost over a weighted average period of 3.3 and 2.2 years, respectively.

8. Income taxes

The Company did not record a provision or benefit for income taxes during the nine months ended September 30, 2021 and 2020. The Company continues to maintain a full valuation allowance against all of its deferred tax assets.

The Company has evaluated the positive and negative evidence involving its ability to realize our deferred tax assets. The Company has considered its history of cumulative net losses incurred since inception and its lack of any commercial products. The Company has concluded that it is more likely than not that it will not realize the benefits of its deferred tax assets. The Company reevaluates the positive and negative evidence at each reporting period.

9. Net loss per common share

Basic and diluted net loss per share attributable to common stockholders is calculated as follows (in thousands except share and per share amounts):

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
Net loss	$ (19,837)	$ (6,558)	$ (50,518)	$ (16,223)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.43)	$ (4.29)	$ (2.85)	$ (11.01)
Weighted-average number of common shares used in computing net loss per share—basic and diluted	45,987,866	1,529,881	17,751,410	1,474,045

The following outstanding potentially dilutive securities have been excluded from the calculation of diluted net loss per common share, as their effect is anti-dilutive:

	September 30, 2021	September 30, 2020
Convertible Preferred Stock	—	53,631,514
Stock options to purchase common stock	5,566,421	481,482
Restricted common stock	296,929	399,004

10. Related parties

Versant Ventures has been a related party since inception of the Company as an investor and member of the board of directors. The Company had a service agreement with a Versant Ventures discovery engine, Ridgeline Therapeutics GmbH, or Ridgeline. Ridgeline provided management and administrative support to facilitate start-up of the Company and provided research and development services. Expenses attributable to Ridgeline were recognized primarily in research and development expenses in the Company's condensed combined and consolidated statements of operations and comprehensive loss. The Company paid $0.5 million and $4.1 million to Ridgeline during the three months ended September 30, 2021 and 2020, respectively. The Company paid $7.8 million and $9.7 million to Ridgeline during the nine months ended September 30, 2021 and 2020, respectively. As of September 30, 2021 and December 31, 2020, the Company had $0 and $4.8 million, respectively, in accounts payable in the condensed consolidated balance sheets associated with Ridgeline. The Company terminated such service agreement on August 9, 2021.

The Company also had a cost sharing agreement with Versant Ventures for the Company's Chief Executive Officer. Amounts recognized as a result of this agreement are recognized in general and administrative expenses in the Company's condensed combined and consolidated statements of operations and comprehensive loss. The Company received $40,000 and $36,000 from Versant Ventures during the three months ended September 30, 2021 and 2020, respectively, related to this agreement. The Company received $160,000 and paid $94,000 to Versant Ventures during the nine months ended September 30, 2021 and 2020, respectively, related to this agreement. As of September 30, 2021 and December 31, 2020, the Company had $0 and $79,000, respectively, in prepaids and other current assets in the condensed consolidated balance sheets related to this agreement.

The Institute for Cancer Research, or the ICR, has been a related party since inception of the Company. The Company had a license, collaboration and investment agreement with the ICR. The Company paid $0 and $584,000 to ICR during the three months ended September 30, 2021 and 2020, respectively. The Company paid $0 and $1.2 million to ICR during the nine months ended September 30, 2021 and 2020, respectively. As of September 30, 2021 and December 31, 2020, no amounts were owed by the Company to ICR.

11. Employee retirement plans

The Company, in compliance with Swiss Law, is contracted with the Swiss Life Collective BVG Foundation for the provision of pension benefits in a defined benefit plan. All benefits are reinsured in their entirety with Swiss Life Ltd within the framework of the contract. The technical administration and management of the savings account are guaranteed by Swiss Life on behalf of the collective foundation. Insurance benefits due are paid directly to the entitled persons by Swiss Life in the name of and for the account of the collective foundation. The pension plan is financed by contributions of both employees and employer. The contract between the Company and the collective foundation can be terminated by either side. In the event of a termination, the Company would have an obligation to find alternative pension arrangements for its employees. Because there is no guarantee that the employee pension arrangements would be continued under the same conditions, there is a risk, albeit remote, that a pension obligation may fall on the Company. The pension assets are pooled for all affiliated companies; the investment of assets is done by the governing bodies of the collective foundation or by mandated parties. The risks of disability, death and longevity are reinsured in their entirety with Swiss Life Ltd. The Company recorded $132,000 and $14,000 defined benefit related expense during the three months ended September 30, 2021 and 2020, respectively. The Company recorded $319,000 and $14,000 defined benefit related expense during the nine months ended September 30, 2021 and 2020, respectively.

In February 2021, the Company adopted a defined contribution plan intended to qualify under Section 401(k) of the Internal Revenue Code covering all eligible U.S. based employees of the Company. All employees are eligible to become participants of the plan immediately upon hire. Each active employee may elect, voluntarily, to contribute a percentage of their compensation to the plan each year, subject to certain limitations. The Company reserves the right, but is not obligated, to make additional contributions to this plan. The Company makes safe-harbor match contributions of 100% of the first 4% of each participant's eligible compensation. The Company recorded $89,000 and $0 matching 401(k) contribution related expense during the three months ended September 30, 2021 and 2020, respectively. The Company recorded $187,000 and $0 matching 401(k) contribution related expense during the nine months ended September 30, 2021 and 2020, respectively.

12. Subsequent events

The Company has evaluated subsequent events through the date these financial statements were issued and has determined that there have been no events that have occurred that would require adjustments to the Company's disclosures in the condensed combined and consolidated financial statements.

Item 2. Management’s discussion and analysis of financial condition and results of operations

The following discussion and analysis should be read in conjunction with the unaudited condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report. This discussion and analysis and other parts of this Quarterly Report contain forward-looking statements based upon current beliefs, plans and expectations that involve risks, uncertainties and assumptions, such as statements regarding our plans, objectives, expectations, intentions and projections. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under Part II, Item 1A, “Risk Factors” and elsewhere in this Quarterly Report. You should carefully read the “Risk Factors” section of this Quarterly Report to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section entitled “Special note regarding forward-looking statements.”

Overview

We are a biotechnology company developing a portfolio of novel small molecule precision medicines that employ the body’s natural mechanisms to selectively degrade therapeutically-relevant proteins. We have developed a proprietary protein degradation platform, called QuEEN, that enables us to rapidly identify protein targets and molecular glue degrader, or MGD, product candidates that are designed to eliminate therapeutically-relevant proteins in a highly selective manner. We believe our small molecule MGDs may give us significant advantages over existing therapeutic modalities, including other protein degradation approaches, by allowing us to target proteins that have been considered undruggable or inadequately drugged. We focus on therapeutic targets backed by strong biological and genetic rationale with the goal of discovering and developing novel precision medicines.

We were incorporated in Delaware in November 2019 and are headquartered in Boston, Massachusetts with research operations in both Boston and Basel, Switzerland. To date, we have been financed primarily through the issuance of convertible promissory notes, convertible preferred stock and, most recently, common stock in our initial public offering, or IPO.

Contribution and exchange

Monte Rosa Therapeutics AG, a Swiss operating company, was incorporated in April 2018. Monte Rosa Therapeutics, Inc. was incorporated in November 2019. In 2020, Monte Rosa Therapeutics, Inc. and Monte Rosa Therapeutics AG, entities under common control since the incorporation of Monte Rosa Therapeutics, Inc., consummated a contribution and exchange agreement, or the Contribution and Exchange, whereby Monte Rosa Therapeutics, Inc. (i) acquired the net assets and shareholdings of Monte Rosa Therapeutics AG via a one-for-one exchange of equity between Monte Rosa Therapeutics, Inc. and the shareholders of Monte Rosa Therapeutics AG in a common control reorganization. Accordingly, the historical financial information has been retrospectively adjusted to include the historical results and financial position of the Company combined with Monte Rosa Therapeutics AG’s historical results and financial position, after the elimination of all intercompany accounts and transactions.

Liquidity

Since inception, we have had significant operating losses. Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures and, to a lesser extent, general and administrative expenditures. Our net loss was $35.9 million and $7.7 million for the years ended December 31, 2020 and 2019, respectively, and our net loss was $50.5 million for the nine months ended September 30, 2021. As of September 30, 2021, we had an accumulated deficit of $98.6 million and $367.0 million in cash and cash equivalents. In February 2021, we issued 24,000,000 shares of our Series B Preferred Stock pursuant to the Company’s Series B Preferred Stock tranche obligation for aggregate gross proceeds of $48.0 million. In March 2021, we authorized the sale of up to 32,054,521 shares of the Company's Series C convertible preferred stock at a price of $2.9637 per share, or Series C Preferred, and issued the authorized shares of Series C Preferred to several new and existing investors for aggregate gross proceeds of $95.0 million. In June 2021 we completed our IPO, of an aggregate of 11,700,000 shares of common stock at a price to the public of $19.00 per share We received aggregate net proceeds from the IPO of $203.9 million, after deducting underwriting discounts and commissions of $15.6 million, and offering costs of $2.9 million. An additional 1,755,000 shares were issued upon the exercise by the underwriters in July of 2021 of their option to purchase additional shares of common stock for which the Company received $31.0 million after deducting underwriter discounts and commissions of $2.3 million.

Business effects of COVID-19

The current COVID-19 pandemic has presented a substantial public health and economic challenge around the world and is affecting our employees, patients, communities and business operations, as well as the U.S. economy and financial markets. To date, our financial conditions and operations have not been significantly impacted by the COVID-19 outbreak; however, the full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations, liquidity and financial condition will depend on future developments, which are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19, the emergence of variants, the actions taken to contain it or treat its impact, including vaccination efforts, and the economic impact on local, regional, national and international markets.

To date, our vendors have been able to continue to provide services and supply reagents, materials, and products and currently do not anticipate any disruption in services or interruptions in supply. However, we are continuing to assess the potential impact of the COVID-19 pandemic on our business and operations, including our expenses, and our ability to hire and retain employees.

The COVID-19 pandemic has caused us to modify our business practices (including but not limited to curtailing or modifying employee travel, moving to partial remote work, and cancelling physical participation in meetings, events and conferences), and we may take further actions as may be required by government authorities or that we determine are in the best interests of our employees, patients and business partners.

Our office-based employees have been working from home since March 2020, while ensuring essential staffing levels in our operations remain in place, including maintaining key personnel in our laboratories.

For additional information on the various risks posed by the COVID-19 pandemic, please read the section entitled “Risk factors” in this Quarterly Report on Form 10-Q.

Components of operating results

Research and development expenses

Our research and development expenses include:

- expenses incurred under agreements with consultants, third-party service providers that conduct research and development activities on our behalf;
- personnel costs, which include salaries, benefits, pension and stock-based compensation;
- laboratory and vendor expenses related to the execution of preclinical studies;
- laboratory supplies and materials used for internal research and development activities; and
- facilities and equipment costs.

Most of our research and development expenses have been related to the development of our QuEEN platform and discovery and lead optimization efforts of our GSPT1 program. We have not reported program costs since our inception because we have not historically tracked or recorded our research and development expenses on a program-by-program basis. We use our personnel and infrastructure resources across the breadth of our research and development activities, which are directed toward identifying and developing product candidates.

We expense all research and development costs in the periods in which they are incurred. Costs for certain research and development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and third-party service providers.

We expect our research and development expenses to increase substantially for the foreseeable future as we continue to invest in research and development activities related to developing our product candidates, including investments in manufacturing, as we advance our programs and conduct clinical trials. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain. As a result, we are unable to determine the duration and completion costs of our research and development projects, the costs of related clinical development costs or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates.

General and administrative expenses

Our general and administrative expenses consist primarily of personnel costs and other expenses for outside professional services, including legal fees relating to patent and corporate matters, professional fees for accounting, auditing, tax and administrative consulting services, insurance costs and other operating costs. We expect our general and administrative expenses to increase over the next several years to support our continued research and development activities, manufacturing activities, and the potential commercialization of our product candidates and development of commercial infrastructure. We also anticipate our general and administrative costs will increase with respect to the hiring of additional personnel, fees to outside consultants, lawyers and accountants, and increased costs associated with being a public company, such as expenses related to services associated with maintaining compliance with Nasdaq listing rules and SEC reporting requirements, insurance and investor relations costs.

Non-operating income and (expense)

Our non-operating income and (expense) includes (i) interest earned on our investments, including principally U.S. government-backed money-market funds; (ii) gains and losses on transactions of our Swiss subsidiary denominated in currencies other than the U.S. Dollar; and (iii) changes in the fair value of our preferred stock tranche obligations.

Results of operations for the three months ended September 30, 2021 and 2020

The following sets forth our results of operations:

	Three months ended September 30,		
(in thousands)	**2021**	**2020**	**Dollar change**
Operating expenses:			
Research and development	$ 15,115	$ 5,472	$ 9,643
General and administrative	4,753	914	3,839
Total operating expenses	19,868	6,386	13,482
Loss from operations	(19,868)	(6,386)	(13,482)
Other income (expense)	31	(172)	203
Net loss	$ (19,837)	$ (6,558)	$ (13,279)

Research and development expenses

Research and development expenses were comprised of:

	Three months ended September 30,		
(in thousands)	**2021**	**2020**	**Dollar change**
External research and development services	$ 6,449	$ 3,628	$ 2,821
Personnel costs	5,392	900	4,492
Laboratory and related expenses	1,586	318	1,268
Facility costs and other expenses	1,688	626	1,062
Research and development expenses	$ 15,115	$ 5,472	$ 9,643

As of September 30, 2021 and September 30, 2020, respectively, we had 73 and 18 employees engaged in research and development activities in our facilities in the United States and Switzerland.

Our research and development activities consist primarily of costs associated with the development of our QuEEN platform and discovery and lead optimization efforts of our GSPT1 program. The increase for the three months ended September 30, 2021 as compared to 2020 was primarily due to the expansion of research and development activities in the United States and Switzerland including increased headcount and facilities, as well as corresponding increases in laboratory related expenses.

General and administrative expenses

General and administrative expenses to support our business activities were comprised of:

	Three months ended September 30,		
(in thousands)	**2021**	**2020**	**Dollar change**
Personnel costs	$ 2,750	$ 573	$ 2,177
Professional services	772	218	554
Facility costs and other expenses	1,231	123	1,108
General and administrative expenses	$ 4,753	$ 914	$ 3,839

As of September 30, 2021 and September 30, 2020, respectively, we had 19 and 4 employees engaged in general and administrative activities principally in our U.S. facility. Personnel and professional service costs increased in the three months ended September 30, 2021 as compared to 2020 as a result of increased headcount and expenses in support of our growth.

Other income (expense)

Other income (expense), net was comprised of:

(in thousands)	Three months ended September 30, 2021	2020
Interest income (expense), net	$ 13	$ 2
Foreign currency exchange gain (loss), net	18	(174)
Other income (expense)	$ 31	$ (172)

Following the contribution and exchange transactions and our Series A-2 convertible preferred stock financing in April 2020, we began investing a portion of our capital in U.S. government backed money market funds held in a custodial account.

Foreign exchange losses on transactions of our Swiss subsidiary denominated currencies in other than the U.S. dollar decreased in the three months ended September 30, 2021 as to compared to the three months ended September 30, 2020 principally due to the lack of volatility of the U.S. Dollar with respect to, principally, the Swiss franc.

Results of operations for the nine months ended September 30, 2021 and 2020

The following sets forth our results of operations:

(in thousands)	Nine months ended September 30, 2021	2020	Dollar change
Operating expenses:			
Research and development	$ 39,025	$ 14,142	$ 24,883
General and administrative	10,470	1,932	8,538
Total operating expenses	49,495	16,074	33,421
Loss from operations	(49,495)	(16,074)	(33,421)
Other expense	(1,023)	(149)	(874)
Net loss	$ (50,518)	$ (16,223)	$ (34,295)

Research and development expenses

Research and development expenses were comprised of:

(in thousands)	Nine months ended September 30, 2021	2020	Dollar change
External research and development services	$ 18,436	$ 11,202	$ 7,234
Personnel costs	11,935	1,361	10,574
Laboratory and related expenses	4,144	519	3,625
Facility costs and other expenses	4,510	1,060	3,450
Research and development expenses	$ 39,025	$ 14,142	$ 24,883

As of September 30, 2021 and September 30, 2020, respectively, we had 73 and 18 employees engaged in research and development activities in our facilities in the United States and Switzerland.

Our research and development activities consist primarily of costs associated with the development of our QuEEN platform and discovery and lead optimization efforts of our GSPT1 program. The increase for the nine months ended September 30, 2021 as compared to 2020 was primarily due to the expansion of research and development activities in the United States and Switzerland, including increased headcount and facilities, as well as corresponding increases in laboratory related expenses.

General and administrative expenses

General and administrative expenses to support our business activities were comprised of:

(in thousands)	Nine months ended September 30, 2021	2020	Dollar change
Personnel costs	$ 6,414	$ 1,118	$ 5,296
Professional services	1,960	468	1,492
Facility costs and other expenses	2,096	346	1,750
General and administrative expenses	$ 10,470	$ 1,932	$ 8,538

As of September 30, 2021 and September 30, 2020, respectively, we had 19 and 4 employees engaged in general and administrative activities principally in our U.S. facility. Personnel and professional service costs increased in the nine months ended September 30, 2021 as compared to 2020 as a result of increased headcount and expenses in support of our growth.

Other income (expense)

Other income (expense), net was comprised of:

(in thousands)	Nine months ended September 30, 2021	2020
Interest income (expense), net	$ 33	$ —
Foreign currency exchange gain (loss), net	(96)	(149)
Changes in fair value of preferred stock tranche obligations, net	(960)	—
Other income (expense)	$ (1,023)	$ (149)

Following the contribution and exchange transactions and our Series A-2 convertible preferred stock financing in April 2020, we began investing a portion of our capital in U.S. government backed money market funds held in a custodial account.

Foreign exchange losses on transactions of our Swiss subsidiary denominated currencies in other than the U.S. dollar increased in the nine months ended September 30, 2021 as to compared to the nine months ended September 30, 2020 principally due to increased growth in operations compared to the prior year, combined with a weakening of the U.S. Dollar with respect to, principally, the Swiss franc.

The changes in the fair value of our preferred stock tranche obligations is principally attributable to assumptions with respect to our overall enterprise value.

Liquidity and capital resources

Overview

We were incorporated in November 2019 and our operations to date have been financed primarily through the issuance of convertible promissory notes, convertible preferred stock and, most recently, common stock in our IPO. As of September 30, 2021, we had $367.0 million in cash and cash equivalents. We have incurred losses since our inception and, as of September 30, 2021, we had an accumulated deficit of $98.6 million. Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures, and to a lesser extent, general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

Cash flows

The following table summarizes our cash flows for the periods indicated:

(in thousands)	Nine months ended September 30, 2021	2020
Net cash (used in) provided by:		
Operating activities	$ (45,191)	$ (14,479)
Investing activities	(6,606)	(2,203)
Financing activities	377,697	60,070
Net increase in cash, cash equivalents and restricted cash	$ 325,900	$ 43,388

Operating activities

Net cash used in operating activities of $45.2 million during the nine months ended September 30, 2021 was attributable to our net loss of $50.5 million and a net decrease in our working capital of $0.3 million, offset by non-cash charges of $5.6 million principally with respect to changes in fair value of our preferred stock tranche obligation, depreciation expense and stock-based compensation.

Net cash used in operating activities of $14.5 million during the nine months ended September 30, 2020 was attributable to our net loss of $16.2 million, primarily offset by a $1.3 million net increase in our working capital.

Investing activities

For the nine months ended September 30, 2021 and 2020, our investing activities consisted of purchases of property and equipment of $6.6 million and $2.2, respectively, as we expanded our operations.

Financing activities

Net cash provided by financing activities for the nine months ended September 30, 2021 amounted to $377.7 million comprised principally of aggregate net proceeds upon the issuance of our Series B and Series C convertible preferred stock in February and March 2021 and the issuance of common stock in our IPO in June 2021.

Net cash provided by financing activities for the nine months ended September 30, 2020 amounted to $60.1 million comprised principally of aggregate net proceeds upon the issuance of our Series A-2 convertible preferred stock in April 2020.

Funding requirements

Any product candidates we may develop may never achieve commercialization and we anticipate that we will continue to incur losses for the foreseeable future. We expect that our research and development expenses, general and administrative expenses, and capital expenditures will continue to increase. As a result, until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements. Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, third-party clinical research, manufacturing and development services, costs relating to the build-out of our headquarters, laboratories and manufacturing facility, license payments or milestone obligations that may arise, laboratory and related supplies, clinical costs, manufacturing costs, legal and other regulatory expenses and general overhead costs.

Based upon our current operating plan, we believe that our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements for at least the next twelve months. We base this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

We will continue to require additional financing to advance our current product candidates through clinical development, to develop, acquire or in-license other potential product candidates and to fund operations for the foreseeable future. We will continue to seek funds through equity offerings, debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies. If we are unable to raise capital, we will need to delay, reduce or terminate planned activities to reduce costs.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, progress, results and costs of researching, developing and manufacturing our current product candidates or any future product candidates, and conducting preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals or clearances for our lead product candidates or any future product candidates;
- the number and characteristics of any additional product candidates we develop or acquire;

- the cost of manufacturing our lead product candidate or any future product candidates and any products we successfully commercialize, including costs associated with building-out our manufacturing capabilities;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of any such agreements that we may enter into;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company;
- the timing, receipt and amount of sales of any future approved or cleared products, if any; and
- the impact of the COVID-19 pandemic and the corresponding responses of businesses and governments.

Further, our operating plans may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials and other research and development activities. We currently have no credit facility or committed sources of capital. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated product development programs.

Critical accounting policies and significant judgments and estimates

Our unaudited interim condensed consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States. The preparation of our unaudited interim condensed consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our condensed financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. However, even though we believe we have used reasonable estimates and assumptions in preparing our interim condensed consolidated financial statements, the future effects of the COVID-19 pandemic on our results of operations, cash flows, and financial position are unclear. Our actual results may differ from these estimates under different assumptions or conditions.

There have been no material changes to our contractual obligations and commitments from those described under “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in the final prospectus for the Company’s IPO filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on June 25, 2021.

Recently issued and adopted accounting pronouncements

Refer to Note 2, “Summary of Significant Accounting Policies,” in the accompanying notes to our combined and consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q for a discussion of recent accounting pronouncements.

Contractual obligations and commitments

During the three months ended September 30, 2021, there have been no material changes to our contractual obligations and commitments from those described under “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in the final prospectus for the Company’s IPO filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on June 25, 2021.

Off-balance sheet arrangements

During the periods presented, we did not have, nor do we currently have, any off-balance sheet arrangements as defined under SEC rules.

Emerging growth company status

In April 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an “emerging growth company” may take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Therefore, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this extended transition period and, as a result, we may adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-public companies instead of the dates required for other public companies. However, we may early adopt these standards.

Item 3. Quantitative and qualitative disclosures about market risk

Interest rate risk

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. We held cash and cash equivalents of $367.0 million as of September 30, 2021. We generally have held our cash equivalents in interest-bearing, U.S. government backed money market funds. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term maturities of our cash equivalents and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents.

Foreign currency exchange risk

Our results of operations are subject to foreign currency exchange rate fluctuations principally due to our operations in Switzerland. As a result, our combined and consolidated financial position, results of operations and cash flows can be affected by market fluctuations in foreign currency exchange rates, primarily with respect to the Swiss franc and the Euro. Fluctuations in the foreign currency exchange rates will affect our operating results, often in ways that are difficult to predict. In particular, as the U.S. dollar weakens versus other currencies the non-U.S. expense will increase when reported in U.S. dollars.

Item 4. Controls and procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of the end of the period covered by this report. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this report were not effective for the reasons set forth below.

In connection with the audit of our consolidated financial statements for each of the periods ended December 31, 2019 and 2020, our management identified material weaknesses in our internal control over financial reporting which remain unremediated. The material weaknesses we identified were (i) we did not maintain an effective control environment as we did not maintain a sufficient complement of accounting and financial reporting resources commensurate with our financial reporting requirements, (ii) we did not maintain an effective risk assessment process, which led to improperly designed controls, (iii) we did not maintain appropriate control activities to support the appropriate segregation of duties over the review of account reconciliations and manual journal entries, and (iv) we did not document, thoroughly communicate and monitor controls processes and relevant accounting policies and procedures. These material weaknesses could result in a misstatement of account balances or disclosures that would result in a material misstatement to the annual or interim financial statements that would not be prevented or detected.

Remediation Plan

We are committed and are taking steps necessary to remediate the control deficiencies that constituted the above material weakness by implementing changes to our internal control over financial reporting. During the last quarter of 2020 and through September 30, 2021, we made the following enhancements to our control environment including the following:

- We added finance personnel to the organization to strengthen our internal accounting team including a vice president of finance and corporate controller.
- We engaged accounting advisory consultants to provide additional depth and breadth in our technical accounting and financial reporting capabilities.

- We implemented a new ERP system which provides a stronger internal control infrastructure for financial reporting and for our internal control procedures
- We established a disclosure committee, ongoing senior management review, and audit committee oversight

Our remediation activities are continuing through the remainder of 2021. In addition to the above activities, we expect to engage in additional activities including:

- Engage internal control consultants to assist us in evaluating and documenting the design of our internal controls that address the relevant risks, identify any gaps in the internal control environment that require remediation, and perform tests of our system of internal controls to monitor operating effectiveness of our internal controls.
- Further develop and document our accounting policies and financial reporting procedures
- Hire additional qualified accounting and finance personnel to provide needed levels of expertise and maintain appropriate segregation of duties

Changes in Internal Control over Financial Reporting

Except for the remediation efforts of the previously identified material weakness as described above, there was no change in our internal control over financial reporting that occurred during the three months ended September 30, 2021 that materially affected, or were reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving the desired control objectives. Our management recognizes that any control system, no matter how well designed and operated, is based upon certain judgments and assumptions and cannot provide absolute assurance that its objectives will be met. Similarly, an evaluation of controls cannot provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected.

Part II — Other Information

Item 1. Legal proceedings

From time to time, we may become 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 September 30, 2021, 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, in addition to the other information set forth in this Quarterly Report and in other documents that we file with the SEC, in evaluating our business. 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 risks described below are not intended to be exhaustive and are not the only risks that we face. 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 in this Quarterly Report are forward-looking statements. Please also see the section entitled "Special note regarding forward-looking statements."

Risks related to our financial position and capital needs

We are a biotechnology company with a limited operating history and have not generated any revenue to date from drug sales, and may never become profitable.

Biopharmaceutical drug development is a highly speculative undertaking and involves a substantial degree of risk. Since our formation as Monte Rosa Therapeutics AG in 2018, our operations have been limited primarily to organizing and staffing our company, business planning, raising capital, researching and developing our Quantitative and Engineered Elimination of Neosubstrates drug discovery platform, or the QuEEN platform, developing our pipeline, building our intellectual property portfolio and undertaking preclinical studies of our lead program molecules. We have never generated any revenue from drug sales. We have not obtained regulatory approvals for any of our current or future product candidates.

Typically, it takes many years to develop one new pharmaceutical drug from the time it is discovered to when it is available for treating patients. Consequently, any predictions we make about our future success or viability may not be as accurate as they could be if we had a longer operating history. In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors, such as the COVID-19 pandemic. We will need to transition from a company focused on research and early stage development to a company capable of supporting late stage development and commercial activities. We may not be successful in such a transition.

We have incurred significant operating losses since our inception and anticipate that we will incur continued losses for the foreseeable future.

Since our inception, we have focused substantially all of our efforts and financial resources on developing our proprietary QuEEN platform, and our initial pipeline. To date, we have financed our operations primarily through the issuance and sale of convertible promissory notes and our convertible preferred stock to outside investors in private equity financings, as well as our initial public offering. From our inception through the date hereof, we raised an aggregate of $479.1 million of gross proceeds from such transactions. As of September 30, 2021, our cash and cash equivalents and investments were $367.0 million. We have incurred net losses in each year since our inception, and we had an accumulated deficit of $98.6 million as of September 30, 2021. For the years ended December 31, 2020 and 2019, we reported net losses of $35.9 million and $7.7 million, respectively. For the nine months ended September 30, 2021, we reported a net loss of $50.5 million. Substantially all of our operating losses have resulted from costs incurred in connection with our research and initial pipeline programs and from general and administrative costs associated with our operations. We expect to continue to incur significant expenses and increasing operating losses over the next several years and for the foreseeable future. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' deficit and working capital. We expect our expenses to significantly increase in connection with our ongoing activities, as we:

- submit a planned IND application with the U.S. Food and Drug Administration, or FDA, for a GSPT1-directed MGD molecule in the first half of 2022 and, if allowed to proceed, initiate a clinical trial;
- continue preclinical activities for our initial GSPT1, NEK7, CDK2, VAV1 and BCL11A programs;
- prepare and submit IND applications with the FDA for other current and future product candidates;
- complete preclinical studies for current or future product candidates;
- progress MGD molecules from our initial programs through lead optimization;
- initiate and complete clinical trials for current or future product candidates;
- expand and improve the capabilities of our QuEEN platform;
- contract to manufacture our product candidates;
- advance research and development related activities to expand our product pipeline;
- seek regulatory approval for our product candidates that successfully complete clinical development;
- develop and scale up our capabilities to support our ongoing preclinical activities and future clinical trials for our product candidates and commercialization of any of our product candidates for which we may obtain marketing approval;
- maintain, expand and protect our intellectual property portfolio;
- hire additional staff, including clinical, scientific and management personnel; and
- secure facilities to support continued growth in our research, development and commercialization efforts.

In addition, if we obtain marketing approval for our current or future product candidates, we will incur significant expenses relating to sales, marketing, product manufacturing and distribution. Because of the numerous risks and uncertainties associated with developing pharmaceutical drugs, including in light of the ongoing evolution of the COVID-19 pandemic, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

Even if we achieve profitability, we may not be able to sustain or increase our profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our development efforts, obtain product approvals, diversify our offerings or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We are very early in our development efforts. All of our programs are still in the preclinical stages of drug discovery. If we are unable to commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.

Our ability to become profitable depends upon our ability to generate revenue. To date we have not generated any revenue from our product candidates, and we do not expect to generate any revenue from the sale of drugs in the near future. We do not expect to generate revenue from product sales unless and until we complete the development of, obtain marketing approval for, and begin to sell, one or more of our product candidates. We are also unable to predict when, if ever, we will be able to generate revenue from such product candidates due to the numerous risks and uncertainties associated with drug development, including the uncertainty of:

- our plans to submit IND applications to the FDA for the GSPT1 product candidate and future product candidates;
- our ability to timely and successfully complete preclinical studies and clinical trials for our GSPT1, NEK7, CDK2, VAV1 and BCL11A programs, and other current or future product candidates;
- our ability to advance MGD molecules from our non-lead programs through lead optimization;
- our successful initiation, enrollment in and completion of clinical trials, including our ability to generate positive data from any such clinical trials;
- our ability to demonstrate, to the satisfaction of the FDA and comparable regulatory authorities the safety, efficacy, consistent manufacturing quality and acceptable risk-benefit profile of our product candidates for their intended uses;
- our ability to timely receive necessary regulatory approvals from applicable regulatory authorities, including the FDA;

- the costs associated with the development of any additional development programs we identify in-house or acquire through collaborations or other arrangements;
- our ability to establish manufacturing capabilities or make arrangements with third-party manufacturers for clinical supply and commercial manufacturing;
- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our current and future product candidates;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;
- obtaining and maintaining acceptance of our product candidates, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- obtaining and maintaining healthcare coverage and adequate reimbursement;
- the terms and timing of any additional collaboration, license or other arrangement, including the terms and timing of any payments thereunder;
- our ability to enforce and defend intellectual property rights and claims; and
- our ability maintain a continued acceptable safety profile of our product candidates following approval.

We expect to incur significant sales and marketing costs as we prepare to commercialize our current or future product candidates. Even if we initiate and successfully complete pivotal or registration-enabling clinical trials of our current or future product candidates, and our current or future product candidates are approved for commercial sale, and despite expending these costs, our current or future product candidates may not be commercially successful. We may not achieve profitability soon after generating drug sales, if ever. If we are unable to generate revenue, we will not become profitable and may be unable to continue operations without continued funding.

We will need to raise substantial additional funding. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, scale back or discontinue some of our product candidate development programs or future commercialization efforts.

We are currently advancing multiple discovery programs through the preclinical stages of drug discovery across a number of potential indications and we have one program in lead optimization. We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we continue the research and development of, advance the preclinical and clinical activities of, and seek marketing approval for, our current or future product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. We also expect to continue to incur significant costs associated with operating as a public company now that we have completed our initial public offering. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. However, we have estimated our current additional funding needs based on assumptions that may prove to be wrong. Additionally, changing circumstances may cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We cannot be certain that additional funding will be available on acceptable terms, or at all. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of public or private equity offerings, debt financings, governmental funding, collaborations, strategic partnerships and alliances or marketing, distribution or licensing arrangements with third parties. If we are unable to raise capital or generate revenue when needed or on attractive terms, we would be forced to delay, reduce or eliminate our discovery and preclinical development programs or any future commercialization efforts. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

We expect that the net proceeds from our initial public offering, together with our existing cash and cash equivalents, will be sufficient to fund our operations into the third quarter of 2024. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. This estimate also assumes that we do not obtain any additional funding through collaborations or other strategic alliances. Our future capital requirements will depend on, and could increase significantly as a result of, many factors, including:

- the scope, prioritization and number of our research and development programs;
- the costs, timing and outcome of regulatory review of our current or future product candidates;
- the scope, progress, results and costs of drug discovery, preclinical development, laboratory testing and planned clinical trials for our current or future product candidates, including additional expenses attributable to adjusting our development plans (including any supply related matters) in response to the COVID-19 pandemic;
- our ability to establish and maintain additional collaborations on favorable terms, if at all;
- the achievement of milestones or occurrence of other developments that trigger payments under any additional collaboration agreements we obtain;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under future collaboration agreements, if any;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire or in-license other current or future product candidates and technologies;
- the costs of securing manufacturing arrangements for commercial production; and
- the costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory clearances to market our current or future product candidates.

Identifying potential current or future 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 drug sales. In addition, our current or future product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of drugs 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 funding to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

Risks related to our business and industry

Risks related to drug development and regulatory approval

Our approach to the discovery and development of product candidates based on our QuEEN platform is novel, which makes it difficult to predict the time, cost of development and likelihood of successfully developing any product candidates.

Our QuEEN platform is a relatively new technology. Our future success depends on the successful development of this novel product candidate development approach. We have not yet succeeded and may not succeed in demonstrating the efficacy and safety of any of our product candidates in clinical trials or in obtaining marketing approval thereafter. In particular, our ability to successfully target therapeutically-relevant proteins using MGDs requires the successful development of non-heterobifunctional molecules that were rationally designed using our QuEEN platform with a rational drug development process and developing those molecules with the right combination of target proteins and E3 ligases. This is a complex process requiring a number of component parts or biological mechanisms to work in unison to achieve the desired effect. We cannot be certain that we will be able to discover MGDs by matching the right target and its degron with the ideal E3 ligase in a timely manner, or at all. We have not yet initiated a clinical trial of any product candidate and we have not yet assessed the safety of any product candidate in humans. As such, there may be adverse effects from treatment with any of our current or future product candidates that we cannot predict at this time.

As a result of these factors, it is more difficult for us to predict the time and cost of product candidate development, and we cannot predict whether the application of our QuEEN platform will result in the development and marketing approval of any product candidates. Any development problems we experience in the future related to our QuEEN platform or any of our discovery programs may cause significant delays or unanticipated costs or may prevent the development of a commercially viable product. Any of these factors may prevent us from completing our preclinical studies or any clinical trials that we may initiate or commercializing any product candidates we may develop on a timely or profitable basis, if at all.

We may not be successful in our efforts to identify or discover additional product candidates or we may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

A key element of our strategy is to apply our QuEEN platform and product pipeline to address a broad array of targets in various therapeutic areas. The discovery activities that we are conducting may not be successful in identifying product candidates that are useful in treating oncology, inflammatory, immunologic and genetic diseases, and neurodegenerative or other neurologic diseases. Our discovery programs may be unsuccessful in identifying potential product candidates, or our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval.

Because we have limited financial and management resources, we focus on a limited number of discovery programs and product candidates at a time. As a result, we may forego or delay pursuit of opportunities with other current or future product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Our business is dependent on the success of our lead program, and any other product candidates that we advance into the clinic. We cannot be certain that we will be able to obtain regulatory approval for, or successfully commercialize, any of our current or future product candidates.

All of our pipeline programs are in early stages of preclinical drug discovery, including our lead molecules from the GSPT1 program. The preclinical studies and future clinical trials of our current or future product candidates are, and the manufacturing and marketing of our current or future product candidates will be, subject to extensive and rigorous review and regulation by numerous government authorities in the U.S. and in other countries where we intend to test or, if approved, market any of our current or future product candidates. Before obtaining regulatory approvals for the commercial sale of any of our current or future product candidates, we must demonstrate through preclinical studies and clinical trials that each product candidate is safe and effective for use in each target indication. Drug development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our preclinical studies and clinical trials. This process can take many years and may include post-marketing studies and surveillance, which will require the expenditure of substantial resources. Of the large number of drugs in development in the U.S., only a small percentage will successfully complete the FDA regulatory approval process and will be commercialized, with similarly low rates of success for drugs in development in the European Union obtaining regulatory approval from the European Medicines Agency, or EMA. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development and preclinical studies and clinical trials, we cannot assure you that any of our current or future product candidates will be successfully developed or commercialized.

We are not permitted to market our current or future product candidates in the U.S. until we receive approval of a New Drug Application, or an NDA, from the FDA, in the European Economic Area, or EEA, until we receive approval of a marketing authorization applications, or an MAA, from the EMA, or in any other foreign countries until we receive the requisite approval from such countries. Obtaining approval of an NDA or MAA is a complex, lengthy, expensive and uncertain process, and the FDA or EMA may delay, limit or deny approval of any of our current or future product candidates for many reasons, including, among others:

- we may not be able to demonstrate that our current or future product candidates are safe and effective in treating their target indications to the satisfaction of the FDA or applicable foreign regulatory agency;
- the results of our preclinical studies and clinical trials may not meet the level of statistical or clinical significance required by the FDA or applicable foreign regulatory agency for marketing approval;
- the FDA or applicable foreign regulatory agency may disagree with the number, design, size, conduct or implementation of our preclinical studies and clinical trials;
- the FDA or applicable foreign regulatory agency may require that we conduct additional preclinical studies and clinical trials;
- we may be unable to demonstrate that a product candidate’s clinical and other benefits outweigh its safety risks;
- the FDA or applicable foreign regulatory agency may not approve the formulation, labeling or specifications of any of our current or future product candidates;

- the contract research organizations, or CROs, that we retain to conduct our preclinical studies and clinical trials may take actions outside of our control that materially adversely impact our preclinical studies and clinical trials;
- the FDA or applicable foreign regulatory agency may find the data from preclinical studies and clinical trials insufficient to demonstrate that our current or future product candidates' clinical and other benefits outweigh their safety risks;
- the FDA or applicable foreign regulatory agency may disagree with our interpretation of data from our preclinical studies and clinical trials;
- the FDA or applicable foreign regulatory agency may not accept data generated at our preclinical studies and clinical trial sites;
- if our NDA, if and when submitted, is reviewed by an advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;
- the FDA may require development of a Risk Evaluation and Mitigation Strategy, or REMS, as a condition of approval or post-approval;
- the FDA or the applicable foreign regulatory agency may determine that the manufacturing processes or facilities of third-party manufacturers with which we contract do not conform to applicable requirements, including current Good Manufacturing Practices, or cGMPs;
- the FDA or applicable foreign regulatory agency may be delayed in their review processes due to staffing or other constraints arising from the COVID-19 pandemic; or
- the FDA or applicable foreign regulatory agency may change its approval policies or adopt new regulations.

Any of these factors, many of which are beyond our control, could jeopardize our ability to obtain regulatory approval for and successfully market our current or future product candidates. Any such setback in our pursuit of regulatory approval would have a material adverse effect on our business and prospects.

If we experience delays or difficulties in the initiation, enrollment and/or retention of patients in clinical trials, our regulatory submissions or receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue our planned clinical trials on a timely basis or at all for our product candidates if we are unable to recruit and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the U.S. Patient enrollment is a significant factor in the timing of clinical trials. Our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate.

Moreover, some of our clinical trials will compete with other clinical trials that are in the same therapeutic areas as our current or future product candidates, and this competition reduces the number and types of patients available to us, as some patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' current or future product candidates. Because the number of qualified clinical investigators and clinical trial sites is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. There may be limited patient pools from which to draw for clinical studies. In addition to the rarity of some diseases, the eligibility criteria of our clinical studies will further limit the pool of available study participants as we will require that patients have specific characteristics that we can measure or to assure their disease is either severe enough or not too advanced to include them in a study.

Patient enrollment for any of our future clinical trials may be affected by other factors including:

- the size and nature of the patient population;
- competition with other companies for clinical sites or patients;
- the willingness of participants to enroll in our clinical trials in our countries of interest;
- the severity of the disease under investigation;
- availability and efficacy of approved drugs for the disease under investigation;
- the eligibility criteria for the clinical trial in question as defined in the protocol;
- the availability of an appropriate screening test for the indications we are pursuing;

- the perceived risks and benefits of the product candidate under study in relation to other available therapies, including any new products that may be approved for the indications we are investigating;
- the efforts to facilitate timely enrollment in and completion of clinical trials;
- delays in or temporary suspension of the enrollment of patients in our future clinical trials due to the COVID-19 pandemic;
- ability to obtain and maintain patient consents;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- the proximity and availability of clinical trial sites for prospective patients; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

These factors may make it difficult for us to enroll enough patients to complete our clinical trials in a timely and cost-effective manner. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and jeopardize our ability to obtain marketing approval for the sale of our product candidates. Furthermore, even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining participation in our clinical trials through the treatment and any follow-up periods.

The incidence and prevalence for target patient populations of our product candidates have not been established with precision. If the market opportunities for our product candidates are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability will be adversely affected, possibly materially.

The precise incidence and prevalence for the indications being pursued by our current and future product candidates is currently unknown. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on estimates. Our GSPT1 program will develop a product candidate for the treatment of cancers overexpressing one of the Myc family genes, our NEK7 program will develop a product candidate for the treatment of inflammatory diseases, our CDK2 program will develop a product candidate for the treatment of cancers such as ovarian and breast cancers, our VAV1 program will develop a product candidate for the treatment of T and B cell malignancies and autoimmune diseases and our BCL11A program will develop a product candidate for the treatment of sickle cell disease and ß-Thalassemia. The total addressable market opportunity for product candidates from these discovery programs and future product candidates will ultimately depend upon, among other things, its proven safety and efficacy, the diagnosis criteria included in the final label for each, whether our product candidates are approved for sale for these indications, acceptance by the medical community and patient access, product pricing and reimbursement. The number of patients for our product candidates in the United States and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business.

Preclinical and clinical drug development is a lengthy and expensive process, with an uncertain outcome. Our preclinical and clinical programs may experience delays or may never advance, which would adversely affect our ability to obtain regulatory approvals or commercialize our product candidates on a timely basis or at all, which could have an adverse effect on our business.

In order to obtain FDA approval to market a new small molecule product, we must demonstrate the safety and efficacy of our product candidates in humans to the satisfaction of the FDA. To meet these requirements, we will have to conduct adequate and well-controlled clinical trials. Clinical testing is expensive, time-consuming and subject to uncertainty. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical studies that support our planned and future INDs in the United States. We are currently selecting lead development candidates for preclinical development. We cannot be certain of the timely completion or outcome of our preclinical studies and cannot predict if the FDA will allow our proposed clinical programs to proceed or if the outcome of our preclinical studies will ultimately support further development of our programs. We have not yet received authorization to proceed under an IND for any product candidate, and we cannot be sure that we will be able to submit INDs or similar applications with respect to our other product candidates on the timelines we expect, if at all, and we cannot be sure that submission of IND or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin.

Conducting preclinical testing and clinical trials represents is a lengthy, time-consuming and expensive process. The length of time may vary substantially according to the type, complexity and novelty of the program, and often can be several years or more per program. Delays associated with programs for which we are directly conducting preclinical studies may cause us to incur additional operating expenses. The commencement and rate of completion of preclinical studies and clinical trials for a product candidate may be delayed by many factors, including, for example:

- inability to generate sufficient preclinical or other *in vivo* or *in vitro* data to support the initiation of clinical studies;
- timely completion of preclinical laboratory tests, animal studies and formulation studies in accordance with the FDA's good laboratory practice requirements and other applicable regulations;
- approval by an independent Institutional Review Board, or IRB, ethics committee at each clinical site before each trial may be initiated;
- delays in reaching a consensus with regulatory agencies on study design and obtaining regulatory authorization to commence clinical trials;
- delays in reaching agreement on acceptable terms with prospective CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delays in identifying, recruiting and training suitable clinical investigators;
- delays in recruiting suitable patients to participate in our clinical trials;
- delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing;
- insufficient or inadequate supply or quality of product candidates or other materials necessary for use in clinical trials, or delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for clinical trials;
- imposition of a temporary or permanent clinical hold by regulatory authorities;
- developments on trials conducted by competitors for related technology that raises FDA or foreign regulatory authority concerns about risk to patients of the technology broadly, or if the FDA or a foreign regulatory authority finds that the investigational protocol or plan is deficient to meet its stated objectives;
- delays in recruiting, screening and enrolling patients and delays caused by patients withdrawing from clinical trials or failing to return for post-treatment follow-up;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, other third parties or us to adhere to clinical trial protocols;
- failure to perform clinical trials in accordance with the FDA's good clinical practice requirements, or GCPs, or applicable regulatory guidelines in other countries;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits, or occurrence of adverse events in a trial of the same class of agents conducted by other companies;
- changes to the clinical trial protocols;
- clinical sites dropping out of a trial;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- selection of clinical endpoints that require prolonged periods of observation or analyses of resulting data;
- the cost of clinical trials of our product candidates being greater than we anticipate;
- clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon development of such product candidates;
- transfer of manufacturing processes to larger-scale facilities operated by a contract manufacturing organization, or CMO, and delays or failure by our CMOs or us to make any necessary changes to such manufacturing process; and
- third parties being unwilling or unable to satisfy their contractual obligations to us.

Further, conducting clinical trials in foreign countries, as we may do for our product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries. Delays in the completion of any preclinical studies or clinical trials of our product candidates will increase our costs, slow down our product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate product revenue. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Any delays to our preclinical studies or clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize our product candidates and our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects significantly.

The results of preclinical testing and early clinical trials may not be predictive of the results of later preclinical studies and clinical trials, and the results of our planned and future clinical trials may not satisfy the requirements of the FDA or other comparable regulatory authorities. If we cannot replicate the positive results from our preclinical studies of our current or future product candidates in our future clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize our current or future product candidates.

We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe and effective before we can seek marketing approvals for their commercial sale. Positive results from our preclinical studies of our current or future product candidates, and any positive results we may obtain from our early clinical trials of our current or future product candidates, may not necessarily be predictive of the results from required subsequent preclinical studies and clinical trials. Similarly, even if we are able to complete our planned preclinical studies or any clinical trials of our current or future product candidates according to our current development timeline, the positive results from such preclinical studies and clinical trials of our current or future product candidates may not be replicated in subsequent preclinical studies or clinical trial results.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain approval from the FDA or a comparable foreign regulatory authority. If we fail to produce positive results in our planned preclinical studies or clinical trials of any of our current or future product candidates, the development timeline and regulatory approval and commercialization prospects for our current or future product candidates, and, correspondingly, our business and financial prospects, would be materially adversely affected. Thus, even if the results from our initial research and preclinical activities appear positive, we do not know whether subsequent clinical studies we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market any product candidates.

Interim, top-line and preliminary data from our preclinical studies and clinical trials that we announce or publish from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data.

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

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, product candidate or our business. If the interim, topline or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our current or future product candidates, we will not be able to commercialize, or will be delayed in commercializing, our current or future product candidates, and our ability to generate revenue will be materially impaired.

Our current or future product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export, are subject to comprehensive regulation by the FDA and other regulatory agencies in the U.S. and by comparable authorities in other countries. Before we can commercialize any of our current or future product candidates, we must obtain marketing approval from the regulatory authorities in the relevant jurisdictions. We have not received approval to market any of our current or future product candidates from regulatory authorities in any jurisdiction, and it is possible that none of our current product candidates, nor any product candidates we may seek to develop in the future, will ever obtain regulatory approval. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate’s safety and efficacy. Securing regulatory approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Our current or future product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

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

If we experience delays in obtaining approval or if we fail to obtain approval of our current or future product candidates, the commercial prospects for our current or future product candidates may be harmed and our ability to generate revenues will be materially impaired.

A pandemic, epidemic, or outbreak of an infectious disease, such as COVID-19, may materially and adversely affect our business and our financial results and could cause a disruption to the development of our product candidates.

In December 2019, a novel strain of the coronavirus disease, COVID-19, was identified in Wuhan, China. This virus has since spread globally and in March 2020, the World Health Organization declared COVID-19 a pandemic. The pandemic and government measures taken in response have also 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 COVID-19, we have implemented policies at our locations to mitigate the risk of exposure to COVID-19 by our personnel, including by limiting the number of staff in any given research and development laboratory or manufacturing facility, a work-from-home policy applicable to our non-laboratory based employees, such as clinical, manufacturing, finance, administrative, quality, regulatory and program managers, and a phased approach to bringing personnel back to our locations over time. As a result of the COVID-19 pandemic, we have experienced and we expect to continue to experience disruptions that could severely impact our business, preclinical studies, including:

- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations, or CMOs, due to staffing shortages, production slowdowns or stoppages, disruptions in delivery systems and the diversion of resources to prioritize manufacturing products that are related to treating or preventing COVID-19;

- interruptions in preclinical studies due to restricted or limited operations at our laboratory facility and those of our sub-contractors;
- delays in necessary interactions with local regulators, institutional review board, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- changes in local regulations as part of a response to the COVID-19 pandemic, which may require us to change the ways in which our preclinical studies are conducted, which may result in unexpected costs, or to discontinue such preclinical studies altogether; and
- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people.

Health regulatory agencies globally may experience disruptions in their operations as a result of the COVID-19 pandemic. The FDA and comparable foreign regulatory agencies may have slower response times or be under-resourced and review, inspection, and other timelines may be materially delayed. As of June 23, 2020, 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 goals. On July 16, 2020, the FDA stated that it is continuing to expedite oncology product development with its staff teleworking full-time. However, the FDA may not be able to continue its current pace and approval timelines could be extended. It is unknown how long these disruptions could continue, were they to occur. Since March 2020, foreign and domestic inspections by the FDA have largely been on hold with the FDA announcing plans in July 2020 to resume prioritized domestic inspections. 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. Any delay in regulatory review resulting from such disruptions could materially affect the development and study of our product candidates.

The global COVID-19 pandemic continues to rapidly evolve. The extent to which COVID-19 impacts our business, results of operations and financial condition will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, duration of the outbreak, travel restrictions, new information that may emerge concerning the severity of COVID-19 or the effectiveness of actions taken in the United States and other countries to contain COVID-19 or treat its impact, among others. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions, but if we or any of the third parties with whom we engage, including the suppliers, service providers, regulators and other third parties with whom we conduct business, were to experience prolonged business shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted.

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

We have not evaluated any product candidates in human clinical trials. Undesirable side effects caused by our current or future product candidates could cause us to interrupt, delay or halt preclinical studies or could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities. As is the case with many treatments for cancer, inflammatory and autoimmune diseases, neurodegeneration or genetic diseases it is likely that there may be adverse side effects associated with the use of our product candidates. Additionally, a potential risk in any protein degradation product is that healthy proteins or proteins not targeted for degradation will be degraded or that the degradation of the targeted protein, in itself, could cause adverse events, undesirable side effects, or unexpected consequences. It is possible that healthy proteins or proteins not targeted for degradation could be degraded using our degrader molecules in any of our planned or future clinical studies. There is also the potential risk of delayed adverse events following treatment using any of our current or future product candidates.

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

Further, our current or future product candidates could cause undesirable side effects in clinical trials related to on-target toxicity. If on-target toxicity is observed, or if our current or future product candidates have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many compounds that initially showed promise in early-stage testing for treating cancer or other diseases have later been found to cause side effects that prevented further development of the compound.

In addition, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of our current or future product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate. In any such event, our studies could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The side effects experienced could affect patient recruitment or the ability of enrolled subjects to complete the study or result in potential product liability claims. Moreover, if we elect, or are required, not to initiate, or to delay, suspend or terminate any future clinical trial of any of our product candidates, the commercial prospects of such product candidates may be harmed and our ability to generate product revenues from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to develop other product candidates, and may harm our business, financial condition and prospects significantly.

In addition, if our current or future product candidates receive marketing approval and we or others identify undesirable side effects caused by such current or future product candidates after such approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may suspend, withdraw or limit approvals of such current or future product candidates, or seek an injunction against their manufacture or distribution;
- regulatory authorities may require the addition of labeling statements or warnings, such as a “boxed” warning or a contraindication;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way such current or future product candidates are distributed or administered, conduct additional clinical trials or change the labeling of the current or future product candidates;
- we may be required to conduct post-marketing studies or change the way the product is administered;
- regulatory authorities may require a REMS plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools;
- we may be subject to regulatory investigations and government enforcement actions;
- we may decide to remove such current or future product candidates from the market;
- we could be sued and held liable for injury caused to individuals exposed to or taking our current or future product candidates;
- we may be subject to fines, injunctions or imposition of criminal penalties; and
- our reputation may suffer.

We believe that any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidates and could substantially increase the costs of commercializing our current or future product candidates, if approved, and significantly impact our ability to successfully commercialize our current or future product candidates and generate revenues.

We may seek and fail to obtain Breakthrough Therapy Designation or Fast Track Designation from the FDA for our current or future product candidates. Even if granted for any of our current or future product candidates, these programs may not lead to a faster development, regulatory review or approval process, and such designations do not increase the likelihood that any of our product candidates will receive marketing approval in the United States.

We may seek a Breakthrough Therapy Designation for one or more of our current or future product candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Product candidates designated as breakthrough therapies by the FDA may also be eligible for priority review and accelerated approval. Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our current or future 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 current or future product candidate may not result in a faster development process, review or approval compared to drugs 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 current or future product candidates qualify as breakthrough therapies, the FDA may later decide that such product candidates no longer meet the conditions for qualification and rescind the designation or decide that the time period for FDA review or approval will not be shortened.

We may also seek Fast Track Designation for one or more of our current or future product candidates. If a product candidate is intended for the treatment of a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address an unmet medical need for this condition, the product sponsor may apply for Fast Track Designation. The sponsor of a product candidate with Fast Track Designation has opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA is submitted, the product candidate may be eligible for priority review. Such product candidate may also be eligible for rolling review, where the FDA may consider to review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular current or future 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 for certain current or future product candidates, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may rescind fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track Designation alone does not guarantee qualification for the FDA’s priority review procedures.

We may seek Orphan Drug Designation for certain of our current or future product candidates, and we may be unsuccessful or may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for market exclusivity.

As part of our business strategy, we may seek Orphan Drug Designation for certain indications of our current or future product candidates, and we may be unsuccessful. Regulatory authorities in some jurisdictions, including the U.S. and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the U.S., or a patient population of 200,000 or more 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 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.

Similarly, in Europe, the European Commission, upon the recommendation of the EMA’s Committee for Orphan Medicinal Products, grants Orphan Drug Designation to promote the development of drugs that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than 5 in 10,000 persons in Europe and for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or the product would be a significant benefit to those affected). Additionally, designation is granted for drugs intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in Europe would be sufficient to justify the necessary investment in developing the drug. In Europe, Orphan Drug Designation entitles a party to financial incentives such as reduction of fees or fee waivers.

Generally, if a product with an Orphan Drug Designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for the same drug for the same indication for that time period. The applicable period is seven years in the U.S. and ten years in the European Union. The exclusivity period in the European Union can be reduced to six years if a drug no longer meets the criteria for Orphan Drug Designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan Drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product candidate from competition because different therapies can be approved for the same condition and the same therapies can be approved for different conditions but used off-label. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Orphan Drug Designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. While we may seek Orphan Drug Designation for applicable indications for our current and any future product candidates, we may never receive such designations. Even if we do receive such designations, there is no guarantee that we will enjoy the benefits of those designations.

Even if we receive marketing authorization for our product candidates, we will be subject to extensive 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 the FDA or a comparable foreign regulatory authority approves any of our current or future product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the drug will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration requirements, and continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. Any regulatory approvals that we receive for our current or future product candidates may also be subject to limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the drug. Later discovery of previously unknown problems with a drug, 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, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- manufacturing delays and supply disruptions where regulatory inspections identify observations of noncompliance during remediation;
- revisions to the labeling, including limitation on approved uses or the addition of warnings, contraindications, or other safety information, including boxed warnings;
- imposition of a REMS, which may include distribution or use restrictions;
- requirements to conduct additional post-market clinical trials to assess the safety of the product;
- fines, warning or 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 approvals;
- product seizure or detention, or refusal to permit the import or export of drugs; and
- injunctions or the imposition of civil or criminal penalties.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

The FDA’s and other regulatory authorities’ policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our current or future product candidates. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States 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 lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Even if we receive marketing approval for our current or future product candidates in the U.S., we may never receive regulatory approval to market our current or future product candidates outside of the U.S.

We plan to seek regulatory approval of our current or future product candidates outside of the U.S. Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction.

For example, even if the FDA grants marketing approval of a product candidate, we may not obtain approvals in other jurisdictions, and comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion and reimbursement of the product candidate in those countries. However, a failure or delay in obtaining marketing approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among countries and can involve additional product candidate testing and administrative review periods different from those in the United States. The time required to obtain approvals in other countries might differ substantially from that required to obtain FDA approval. The marketing approval processes in other countries generally implicate all of the risks detailed above regarding FDA approval in the U.S. as well as other risks. In particular, in many countries outside of the U.S., products must receive pricing and reimbursement approval before the product can be commercialized. Obtaining this approval can result in substantial delays in bringing products to market in such countries.

Obtaining foreign regulatory approvals and establishing and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any future collaborator fail to comply with regulatory requirements in international markets or fail to receive applicable marketing approvals, it would reduce the size of our potential market, which could have a material adverse impact on our business, results of operations and prospects.

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 operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers’ compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

Our future growth may depend, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties that could materially adversely affect our business.

We are not permitted to market or promote any of our current or future product candidates before we receive regulatory approval from the applicable regulatory authority in that foreign market, and we may never receive such regulatory approval for any of our current or future product candidates. To obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy. Such requirements govern, among other things, clinical trials and commercial sales, and pricing and distribution of our current or future product candidates, and we cannot predict success in these jurisdictions. If we obtain approval of our current or future product candidates and ultimately commercialize our current or future product candidates in foreign markets, we would be subject to additional risks and uncertainties, including:

- differing regulatory requirements in foreign countries, such that obtaining regulatory approvals outside of the U.S. may take longer and be more costly than obtaining approval in the U.S.;
- our customers’ ability to obtain reimbursement for our current or future product candidates in foreign markets;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer accounts receivable collection times;
- longer lead times for shipping;

- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries;
- the existence of additional potentially relevant third-party intellectual property rights;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

Foreign sales of our current or future product candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs.

Changes in funding or disruptions at the FDA, the SEC and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

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

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, including for 35 days beginning on December 22, 2018, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products, and on March 18, 2020 the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Since March 2020, 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 prioritized domestic inspections and resumed inspections in China and India in early 2021. In April 2021, the FDA issued guidance for industry formally announcing plans to employ remote interactive evaluations, using risk management methods, to meet user fee commitments and goal dates. Should the FDA determine that a manufacturing or bioresearch monitoring 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. Further, if there is inadequate information to make a determination on the acceptability of a facility, the FDA may defer action on the application until an inspection can be completed. In 2020, several companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Future government shutdowns or delays could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

We may in the future conduct clinical trials for current or future product candidates outside the U.S., and the FDA and comparable foreign regulatory authorities may not accept data from such trials.

We may in the future choose to conduct one or more clinical trials outside the U.S., including in Europe. The acceptance of study data from clinical trials conducted outside the U.S. or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the U.S., the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the study is well-designed and well-conducted in accordance with GCP and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the U.S. or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations.

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, which we collectively refer to as Trade Laws, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations.

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenues, if any.

In some countries, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidates. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after coverage and reimbursement have been obtained. Reference pricing used by various countries and parallel distribution or arbitrage between low-priced and high-priced countries, can further reduce prices. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies, which is time-consuming and costly. If coverage and reimbursement of our product candidates are unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

Risks related to commercialization

Even if we receive marketing approval for our current or future product candidates, our current or future product candidates may not achieve broad market acceptance, which would limit the revenue that we generate from their sales.

The commercial success of our current or future product candidates, if approved by the FDA or other applicable regulatory authorities, will depend upon the awareness and acceptance of our current or future product candidates among the medical community, including physicians, patients and healthcare payors. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant revenue and we may not become profitable. Market acceptance of our current or future product candidates, if approved, will depend on a number of factors, including, among others:

- the efficacy of our current or future product candidates as demonstrated in clinical trials, and, if required by any applicable regulatory authority in connection with the approval for the applicable indications, to provide patients with incremental health benefits, as compared with other available medicines;
- the timing of market introduction of the product candidates and potential advantages to alternative treatments;
- limitations or warnings contained in the labeling approved for our current or future product candidates by the FDA or other applicable regulatory authorities;
- the clinical indications for which our current or future product candidates are approved;
- availability of alternative treatments already approved or expected to be commercially launched in the near future;
- the potential and perceived advantages of our current or future product candidates over current treatment options or alternative treatments, including future alternative treatments;
- the willingness of the target patient population to try new therapies or treatment methods and of physicians to prescribe these therapies or methods;
- the need to dose such product candidates in combination with other therapeutic agents, and related costs;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments;
- pricing and cost effectiveness;
- the effectiveness of our sales and marketing strategies;
- our ability to increase awareness of our current or future product candidates;
- our ability to obtain sufficient third-party coverage or reimbursement; or
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage.

If our current or future product candidates are approved but do not achieve an adequate level of acceptance by patients, physicians and payors, we may not generate sufficient revenue from our current or future product candidates to become or remain profitable. Before granting reimbursement approval, healthcare payors may require us to demonstrate that our current or future product candidates, in addition to treating these target indications, also provide incremental health benefits to patients. Our efforts to educate the medical community, patient organizations and third-party payors about the benefits of our current or future product candidates may require significant resources and may never be successful.

If we are unable to establish sales, marketing and distribution capabilities for any product candidate that may receive regulatory approval, we may not be successful in commercializing those product candidates if and when they are approved.

We do not have sales or marketing infrastructure. To achieve commercial success for any product candidate for which we may obtain marketing approval, we will need to establish a sales and marketing organization. In the future, we expect to build a focused sales and marketing infrastructure to market some of our product candidates in the United States, if and when they are approved. There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to market our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians in order to educate physicians about our product candidates, once approved;

- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are unable to establish our own sales, marketing and distribution capabilities and are forced to enter into arrangements with, and rely on, third parties to perform these services, our revenue and our profitability, if any, are likely to be lower than if we had developed such capabilities ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

The market opportunities for any current or future product candidate we develop, if and when approved, may be limited to those patients who are ineligible for established therapies or for whom prior therapies have failed, and may be small.

Cancer therapies are sometimes characterized as first-line, second-line, or third-line, and the FDA often approves new therapies initially only for third-line use. When cancer is detected early enough, first-line therapy, usually chemotherapy, hormone therapy, surgery, radiation therapy or a combination of these, is sometimes adequate to cure the cancer or prolong life without a cure. Second- and third-line therapies are administered to patients when prior therapy is not effective. We expect to initially seek approval of our product candidates we develop as a therapy for patients who have received one or more prior treatments. Subsequently, for those products that prove to be sufficiently beneficial, if any, we would expect to seek approval potentially as a first-line therapy, but there is no guarantee that product candidates we develop, even if approved, would be approved for first-line therapy, and, prior to any such approvals, we may have to conduct additional clinical trials.

The number of patients who have the cancers we are targeting may turn out to be lower than expected. Additionally, the potentially addressable patient population for our current programs or future product candidates in both oncology and non-oncology indications may be limited, if and when approved. Even if we obtain significant market share for any product candidate, if and when approved, if the potential target populations are small, we may never achieve profitability without obtaining marketing approval for additional indications, including to be used as first- or second-line therapy.

We face substantial competition, which may result in others discovering, developing or commercializing drugs before or more successfully than we do.

The development and commercialization of new drugs is highly competitive. We face and will continue to face competition from third parties that use protein degradation, antibody therapy, inhibitory nucleic acid, gene editing or gene therapy development platforms and from companies focused on more traditional therapeutic modalities, such as small molecule inhibitors. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization of new drugs.

We are aware of several biotechnology companies focused on developing molecular glue degraders or MGD therapeutics for patients, including BioTheryX Therapeutics, C4 Therapeutics, Inc., Nurix Therapeutics, Inc., Kymera Therapeutics, Inc., Arvinas, Inc. and Seed Therapeutics, Inc., all of which are currently in development. In addition, lenalidomide and pomalidomide, which are both marketed by Bristol-Myers Squibb, are believed to function as MGDs. Further, several large pharmaceutical companies have disclosed investments in this field.

Many of our current or future competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and reimbursement and marketing of approved drugs than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific, sales, marketing and management personnel and establishing clinical trial sites and patient recruitment for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any drugs that we or our collaborators may develop. Our competitors also may obtain FDA or other regulatory approval for their drugs more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we or our collaborators are able to enter the market. The key competitive factors affecting the success of all of our current or future product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the level of generic competition and the availability of reimbursement from government and other third-party payors.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any current or future product candidates that we may develop.

We will face an inherent risk of product liability exposure related to the testing of our current or future product candidates in human clinical trials and will face an even greater risk if we commercially sell any current or future product candidates that we may develop. If we cannot successfully defend ourselves against claims that our current or future product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any current or future product candidates that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize any current or future product candidates that we may develop.

We do not yet maintain product liability insurance, and we anticipate that we will need to increase our insurance coverage when we begin clinical trials and if we successfully commercialize any product candidate. Insurance coverage is increasingly expensive. We may not be able to maintain product liability insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Even if we are able to commercialize any current or future product candidates, such drugs may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business.

Significant uncertainty exists as to the coverage and reimbursement status of any products for which we may obtain regulatory approval. In the U.S. and in other countries, sales of any products for which we may receive regulatory marketing approval for commercial sale will depend, in part, on the availability of coverage and reimbursement from third-party payors. Third-party payors include government healthcare programs (e.g., Medicare and Medicaid), managed care providers, private health insurers, health maintenance organizations and other organizations. These third-party payors decide which medications they will pay for and establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and other third-party payors is essential for most patients to be able to afford treatments such as targeted protein degradation therapies.

In the United States, no uniform policy exists for coverage and reimbursement for products among third-party payors. Therefore, decisions regarding the extent of coverage and amount of reimbursement to be provided can differ significantly from payor to payor. Third-party payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. Factors payors consider in determining reimbursement are based on whether the 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.

One third-party payor’s decision to cover a particular product or service does not ensure that other payors will also provide coverage for the medical product or service. Third-party payors may limit coverage to specific products on an approved list or formulary, which may not include all FDA-approved products for a particular indication. Also, third-party payors may refuse to include a particular branded product on their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available. We cannot be sure that coverage will be available for any product candidate that we commercialize.

Moreover, the process for determining whether a payor will provide coverage for a product may be separate from the process for setting the reimbursement rate a payor will pay for the product. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. If coverage is available, but reimbursement is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

Further, third-party 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 secure coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA or comparable regulatory approvals. Additionally, we may also need to provide discounts to purchasers, private health plans or government healthcare programs. Despite our best efforts, our product candidates may not be considered medically necessary or cost-effective. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover an approved product as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit. A decision by a third-party payor not to cover a product could reduce physician utilization once the product is approved and have a material adverse effect on sales, our operations and financial condition.

Finally, in some foreign countries, the proposed pricing for a product candidate must be approved before it may be lawfully marketed. The requirements governing product pricing vary widely from country to country. For example, in the European Union, or EU, pricing and reimbursement of pharmaceutical products are regulated at a national level under the individual EU Member States' social security systems. Some foreign countries provide options to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and can control the prices and reimbursement levels of medicinal products for human use. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A country 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. There can be no assurance that any country that has price controls or reimbursement limitations for products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Even if approved for reimbursement, historically, product candidates launched in some foreign countries, such as some countries in the EU, do not follow price structures of the U.S. and prices generally tend to be significantly lower.

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

In the United States and in some foreign jurisdictions, there have been, and likely will continue to be, a number of legislative and regulatory changes and proposed changes intended to broaden access to healthcare, improve the quality of healthcare, and contain or lower the cost of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or the ACA, was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. The ACA, among other things, subjected drug products to potential competition by lower-cost biosimilars, expanded the types of entities eligible for the 340B drug discount program, addressed 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, increased rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs, and created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, or BBA, effective as of January 2019) 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.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA and certain members of Congress have introduced several pieces of legislation aimed at significantly revising or repealing the ACA. The implementation of the ACA is ongoing, the law appears likely to continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs. Litigation and legislation related to the ACA are likely to continue, with unpredictable and uncertain results.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, in August 2011, the Budget Control Act of 2011, among other things, included aggregate reductions of

Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013, and, due to subsequent legislative amendments, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021, unless additional Congressional action is taken. Proposed legislation, if enacted, would extend this suspension through the end of the year; the Centers for Medicare & Medicaid Services, or CMS, has signaled that it is delaying the processing of claims in April 2021 to allow Congress to prevent the reimposition of the 2% cuts during the pandemic. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Furthermore, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several congressional inquiries and proposed legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient assistance programs and reform government program reimbursement methodologies for pharmaceutical and biological products. At the federal level, the previous administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. It is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. It is difficult to predict the future legislative landscape in healthcare and the effect on our business, results of operations, financial condition and prospects. However, we expect that additional state and federal healthcare reform measures will be adopted in the future, particularly in light of the new presidential administration. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

At the state level, individual states are increasingly aggressive in 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. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

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

Our relationships with customers, health care providers, 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, exclusion from government healthcare programs, contractual damages, reputational harm and diminished future profits and earnings.

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any current or future product candidates for which we obtain marketing approval. Our business operations and any current or future arrangements with third-party payors and customers may expose us to broadly applicable federal and state laws relating to fraud and abuse, as well as other healthcare laws and regulations. These laws may impact, among other things, the business or financial arrangements and relationships through which we market, sell and distribute any current or future product candidates for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include, among others:

- the federal Anti-Kickback Statute, which prohibits, among other things, any person or entity from knowingly and willfully soliciting, offering, receiving, providing or paying remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, or arranging for, any item, good, facility, or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations can result in significant civil monetary and criminal penalties for each violation, plus up to three times the amount of remuneration, imprisonment, and exclusion from government healthcare programs. Further, a violation of the federal Anti-Kickback Statute can also form the basis for False Claims Act liability. On December 2, 2020, OIG published 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. Implementation of this change and new safe harbors for point-of-sale reductions in price for prescription pharmaceutical products and pharmacy benefit manager service fees has been delayed by the Biden administration until January 1, 2023, and may be amended or repealed. We continue to evaluate what effect, if any, the rule will have on our business;

- the federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which prohibits individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. Actions under the False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Violations of the False Claims Act can result in very significant monetary penalties for each false claim and three times the amount of the government's damages. Manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false of fraudulent claim for purposes of the False Claims Act;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes additional criminal and civil liability for 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 a material fact or making any materially false statement in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the federal physician payment transparency laws, including the federal Physician Payment Sunshine Act created under the ACA, which requires manufacturers of certain drugs, devices, biologics and medical supplies, among others, to track and disclose payments under Medicare, Medicaid, or the Children's Health Insurance Program (with certain exceptions) and other transfers of value they make to U.S. 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. This information is subsequently made publicly available in a searchable format on a CMS website. Failure to disclose required information may result in civil monetary penalties for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, including the final omnibus rule published on January 25, 2013, which imposes, among other things, certain requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities that create, receive, maintain, transmit, or obtain, protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, 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 attorney's fees and costs associated with pursuing federal civil actions. In addition, there may be additional federal, state and non-U.S. laws which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; and

- analogous state law equivalents of each of the above U.S. federal laws, such as state anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers or patients; state and local marketing and/or transparency laws applicable to manufacturers that may be broader in scope than the federal requirements; state laws that require the reporting of information related to drug pricing; state 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 and pricing information; state and local laws that require the licensure and/or registration of pharmaceutical sales representatives; state 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; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

It is possible that governmental authorities will conclude that our business practices, including our arrangements with certain physicians, some of whom are compensated in the form of stock or stock options for services provided to us, do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are to be found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or similar settlement to resolve allegations of non-compliance with these laws, any of which could adversely affect our ability to operate our business and our financial results. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to similar actions, penalties, and sanctions.

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-bribery laws of EU Member States, such as the U.K. Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment. Payments made to physicians in certain EU Member States must be publicly disclosed. 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.

Risks related to our dependence on third parties

We currently rely, and plan to rely on in the future, on third parties to conduct and support our preclinical studies, and we expect to rely on third parties to conduct our clinical trials for our current and future product candidates. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain marketing approval for or commercialize our current and potential future product candidates and our business could be substantially harmed.

We utilize and depend upon independent investigators and collaborators, such as medical institutions, CROs, CMOs and strategic partners to help conduct our preclinical studies. We do not have the ability to independently conduct clinical trials. We expect to rely on medical institutions, clinical investigators, contract laboratories, and other third parties, including collaboration partners, to conduct or otherwise support clinical trials for our current or future product candidates. We expect to rely heavily on these parties for execution of clinical trials for our product candidates and control only certain aspects of their activities. Nevertheless, we will be responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on CROs will not relieve us of our regulatory responsibilities.

We and any third parties that we contract with are required to comply with regulations and requirements, including GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development, for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial patients are adequately informed of the potential risks of participating in clinical trials and their rights are protected. These regulations are enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for any drugs in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we or the third parties we contract with 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 perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our future clinical trials will comply with GCP requirements. In addition, our clinical trials must be conducted with current or future product candidates produced under cGMP regulations and will require a large number of study subjects. Our failure or the failure of third parties that we may contract with to comply with these regulations or to recruit a sufficient number of subjects may require us to repeat some aspects of a specific, or an entire, clinical trial, which would delay the marketing approval process and could also subject us to enforcement action. We also are required to register certain ongoing clinical trials and provide certain information, including information relating to the trial's protocol, on a government-sponsored database, ClinicalTrials.gov, within specific timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Although we intend to design the clinical trials for our current or future product candidates, or be involved in the design when other parties sponsor the trials, we anticipate that third parties will conduct all of our clinical trials. As a result, many important aspects of our clinical development, including their conduct, timing and response to the ongoing COVID-19 pandemic, will be outside of our direct control. Our reliance on third parties to conduct future clinical trials will also result in less direct control over the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff, and we cannot control whether or not they will devote sufficient time and resources to our product candidates. 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. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues; and
- form relationships with other entities, some of which may be our competitors.

These factors may materially adversely affect the willingness or ability of third parties to conduct our clinical trials and may subject us to unexpected cost increases that are beyond our control. If our CROs do not perform clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development, marketing approval and commercialization of our current or future product candidates may be delayed, we may not be able to obtain marketing approval and commercialize our current or future product candidates, or our development programs may be materially and irreversibly harmed. If we are unable to rely on clinical data collected by our CROs, we could be required to repeat, extend the duration of, or increase the size of any clinical trials we conduct and this could significantly delay commercialization and require significantly greater expenditures.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs on commercially reasonable terms, or at all. If our CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain are compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any clinical trials such CROs are associated with may be extended, delayed or terminated, and we may not be able to obtain marketing approval for or successfully commercialize our current or future product candidates. As a result, we believe that our financial results and the commercial prospects for our current or future product candidates in the subject indication would be harmed, our costs could increase and our ability to generate revenue could be delayed.

The third parties upon whom we rely on for the supply of drug product and starting materials used in our product candidates are limited in number, and the loss of any of these suppliers, or their noncompliance with regulatory requirements or our quality standards, could significantly harm our business.

The drug substance and drug product in our product candidates are supplied to us from a small number of suppliers, and in some cases sole source suppliers. Our ability to successfully develop our current or future product candidates, and to ultimately supply our commercial drugs in quantities sufficient to meet the market demand, depends in part on our ability to obtain the drug product and drug substance for these drugs in accordance with regulatory requirements and in sufficient quantities for commercialization and clinical testing.

The facilities used by our contract manufacturers to manufacture our product candidates will be identified in, and subject to inspections that will be conducted after we submit, any marketing application to the FDA or other comparable foreign regulatory authorities. We may not control the manufacturing process of, and may be completely dependent on, our contract manufacturing partners for compliance with cGMP requirements and any other regulatory requirements of the FDA or other regulatory authorities for the manufacture of our product candidates. Beyond periodic audits, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve our marketing applications identifying these facilities for the manufacture of our product candidates or if it withdraws any approval in the future, we may need to find alternative manufacturing facilities, which would require that we incur significant additional costs and materially adversely affect our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

Similarly, if any third-party manufacturers on which we will rely fail to manufacture quantities of our product candidates at quality levels necessary to meet regulatory requirements and at a scale sufficient to meet anticipated demand at a cost that allows us to achieve profitability, our business, financial condition and prospects could be materially and adversely affected.

Further, we do not currently have arrangements in place for a redundant or second-source supply of all drug product or drug substance in the event any of our current suppliers of such drug product and drug substance cease their operations for any reason. Any delays in the delivery of our drug substance, drug product or starting materials could have an adverse effect and potentially harm our business.

For all of our current or future product candidates, we intend to identify and qualify additional manufacturers to provide drug product and drug substance prior to submission of an NDA to the FDA and/or an MAA to the EMA. We are not certain, however, that our single-source and dual source suppliers will be able to meet our demand for their products, either because of the nature of our agreements with those suppliers, our limited experience with those suppliers or our relative importance as a customer to those suppliers. It may be difficult for us to assess their ability to timely meet our demand in the future based on past performance. While our suppliers have generally met our demand for their products on a timely basis in the past, they may subordinate our needs in the future to their other customers.

Establishing additional or replacement suppliers for the drug product and drug substance used in our current or future product candidates, if required, may not be accomplished quickly. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original supplier and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. If we are able to find a replacement supplier, such replacement supplier would need to be qualified and may require additional regulatory approval, which could result in further delay. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

While we seek to maintain adequate inventory of the drug product and drug substance used in our current or future product candidates, any interruption or delay in the supply of components or materials, or our inability to obtain drug product and drug substance from alternate sources at acceptable prices in a timely manner, could impede, delay, limit or prevent our development efforts, which could harm our business, results of operations, financial condition and prospects.

Our success is dependent on our executive management team's ability to successfully pursue business development, strategic partnerships and investment opportunities as our company matures*. *We may also form or seek strategic alliances or acquisitions or enter into additional collaboration and licensing arrangements in the future, and we may not realize the benefits of such collaborations, alliances, acquisitions or licensing arrangements.

We may in the future form or seek strategic alliances or acquisitions, create joint ventures, or enter into additional collaboration and licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our current product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business.

In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or acquisition or other alternative arrangements for our current or future product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our current or future product candidates as having the requisite potential to demonstrate safety, potency, purity and efficacy and obtain marketing approval.

Further, collaborations involving our technologies or current or future product candidates are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of our current or future product candidates or may elect not to continue or renew development or commercialization of our current or future product candidates based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;

- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our current or future product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our current or future product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable current or future product candidates;
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property; and
- collaborators may not pay milestones and royalties due to the company in a timely manner.

As a result, we may not be able to realize the benefits of our existing collaboration and licensing arrangements or any future strategic partnerships or acquisitions, collaborations or license arrangements we may enter into if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction, license, collaboration or other business development partnership, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to our current or future product candidates could delay the development and commercialization of our current or future product candidates in certain geographies or for certain indications, which would harm our business prospects, financial condition and results of operations.

Manufacturing our current or future product candidates is complex and we may encounter difficulties in production. If we encounter such difficulties, our ability to provide supply of our current or future product candidates for preclinical studies and future clinical trials or for commercial purposes could be delayed or stopped.

The process of manufacturing of our current or future product candidates is complex and highly regulated. We do not have our own manufacturing facilities or personnel and currently rely, and expect to continue to rely, on third parties for the manufacture of our current or future product candidates. These third-party manufacturing providers may not be able to provide adequate resources or capacity to meet our needs and may incorporate their own proprietary processes into our product candidate manufacturing processes. We have limited control and oversight of a third party’s proprietary process, and a third party may elect to modify its process without our consent or knowledge. These modifications could negatively impact our manufacturing, including product loss or failure that requires additional manufacturing runs or a change in manufacturer, either of which could significantly increase the cost of and significantly delay the manufacture of our current or future product candidates.

As our current or future product candidates progress through preclinical studies and clinical trials towards potential approval and commercialization, it is expected that various aspects of the manufacturing process will be altered in an effort to optimize processes and results. Such changes may require amendments to be made to regulatory applications which may further delay the timeframes under which modified manufacturing processes can be used for any of our current or future product candidates and additional bridging studies or trials may be required and may not be successful. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials. Any such delay could have a material adverse impact on our business, results of operations and prospects.

Our manufacturing process needs to comply with FDA regulations relating to the quality and reliability of such processes. Any failure to comply with relevant regulations could result in delays in or termination of our preclinical and future clinical programs and suspension or withdrawal of any regulatory approvals.

In order to commercially produce our products either at our own facility or at a third party’s facility, we will need to comply with the FDA’s cGMP regulations and guidelines. We may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. We and our third party manufacturers are subject to inspections by the FDA and comparable foreign regulatory authorities to confirm compliance with applicable regulatory requirements. Any failure to follow cGMP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our product candidates as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our current or future product candidates, including leading to significant delays in the availability of our product candidates for our future clinical trials or the termination of or suspension of a future clinical trial, or the delay or prevention of a filing or approval of marketing applications for our current or future product candidates. Significant non-compliance could also result in the imposition of sanctions, including warning or untitled letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our current or future product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation and our business.

If our third-party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical materials, by our third-party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the U.S. governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers’ procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

Risks related to intellectual property

If we are unable to obtain and maintain patent and other intellectual property protection for our technology and product candidates or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and drugs may be impaired, and we may not be able to compete effectively in our market.

We rely upon a combination of patents, trademarks, trade secret protection and confidentiality agreements to protect the intellectual property related to our products and technologies and to prevent third parties from copying and surpassing our achievements, thus eroding our competitive position in our market. Our commercial success depends in part on our ability to obtain and maintain patent or other intellectual property protection in the U.S. and other countries for our current or future product candidates and our core technologies, including our proprietary QuEEN platform, our initial GSPT1, NEK7, CDK2, VAV1 and BCL11A programs, which are our five most advanced preclinical stage pipeline programs, as well as our proprietary compound library and other know-how. We seek to protect our proprietary and intellectual property position by, among other methods, filing patent applications in the U.S. and abroad related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business.

We own patent applications related to our QuEEN platform, our CDK2 program, our NEK7 program, and our GSPT1 program, including GSPT1-directed MGDs, biomarkers related to these compounds, and methods of reading through nonsense mutations. We currently do not own any issued patents. Further, patent prosecution related to our pending patent applications is in the early stages and, as such, no patent examiner has yet fully scrutinized the merits of any of our pending patent applications.

As of August 12, 2021, our patent portfolio covering GSPT1-directed MGDs and uses thereof includes seven patent families, our patent portfolio related to our QuEEN platform includes two patent families, our patent portfolio related to our CDK2 program includes one patent family, and our patent portfolio related to our NEK7 program includes one patent family. Patent term adjustments, supplementary protection certificate filings, or patent term extensions could result in later expiration dates in various countries, while terminal disclaimers could result in earlier expiration dates in the U.S.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As such, we cannot guarantee that our pending and future patent applications will result in patents being issued or that issued patents will afford sufficient protection of our product candidates or their intended uses against competitors, nor can there be any assurance that the patents issued will not be infringed, designed around, invalidated by third parties, or effectively prevent others from commercializing competitive technologies, products or product candidates.

The degree of patent protection we require to successfully commercialize our current or future product candidates may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any of our pending patent applications that mature into issued patents will include claims with a scope sufficient to protect our QuEEN platform and our current or future product candidates. In addition, if the breadth or strength of protection provided by our patent applications or any patents we may own or in-license is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Other parties have developed technologies that may be related or competitive to our own, and such parties may have filed or may file patent applications, or may have acquired or may acquire patents, claiming inventions that may overlap or conflict with those claimed in our own patent applications or issued patents, with respect to either the same compounds, methods, formulations or other subject matter, in either case that we may rely upon to dominate our patent position in the market. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until at least 18 months after the earliest priority date of the patent filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in patents we may own or in-license patents or pending patent applications, or that we were the first to file for patent protection of such inventions. In addition, the USPTO might require that the term of a patent issuing from a pending patent application be disclaimed and limited to the term of another patent that is commonly owned or names a common inventor. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights cannot be predicted with any certainty.

In addition, the patent prosecution 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. Further, with respect to certain pending patent applications covering our current or future product candidates or technologies, prosecution has yet to commence and as such, no patent examiner has scrutinized the merits of such pending patent applications. Patent prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the relevant patent office(s) may be significantly narrowed by the time they issue, if they ever do. 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 to third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

Even if we acquire patent protection that we expect should enable us to establish and/or maintain a competitive advantage, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the U.S. and abroad. We may become involved in opposition, derivation, reexamination, *inter partes* review, or post-grant review proceedings challenging our patent rights or the patent rights of others from whom we may in the future obtain licenses to such rights, in the U.S. Patent and Trademark Office, or USPTO, the European Patent Office, or EPO, or the relevant patent authorities in other countries. In addition, we may be subject to third-party submissions to the USPTO, the EPO, or elsewhere, that may reduce the scope or preclude the granting of claims from our pending patent applications. Competitors may challenge our issued patents or may file patent applications before we do. Competitors may also claim that we are infringing their patents and that we therefore cannot practice our technology as claimed under our patents or patent applications. Competitors may also contest our patents by arguing before an administrative patent authority or judge that the invention was not patent-eligible, was not novel, was obvious, and/or lacked inventive steps, and/or that the patent application failed to meet relevant requirements relating to description, basis, enablement, and/or support; in litigation, a competitor could assert that our patents are not valid or are unenforceable for a number of reasons. If a court or administrative patent authority agrees, we would lose our protection of those challenged patents.

An adverse determination in any such submission or proceeding may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and drugs, without payment to us, or could limit the duration of the patent protection covering our technology and current or future product candidates. Such challenges may also result in our inability to manufacture or commercialize our current or future product candidates without infringing third-party patent rights. 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.

Even if they are unchallenged, our issued patents and our pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent patents we may own or in-license by developing similar or alternative technologies or drugs in a non-infringing manner. For example, a third party may develop a competitive drug or product that provides benefits similar to one or more of our current or future product candidates but that has a different composition or otherwise falls outside the scope of our patent protection. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our current or future product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our current or future product candidates could be negatively affected, which would harm our business.

Obtaining and maintaining our patent protection, including patent term, depends on compliance with various procedural, document submission, deadlines, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated if we miss a filing deadline for patent protection on these inventions or otherwise fail to comply with these requirements.

The USPTO and foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after issuance of any patent. In addition, periodic maintenance fees, renewal fees, annuity fees and/or various other government fees are required to be paid periodically. While an inadvertent lapse, including due to the effect of the COVID-19 pandemic on us or our maintenance vendors, can in some 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 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. In such an event, our competitors might be able to enter the market with similar or identical products or platforms, which could have a material adverse effect on our business prospects and financial condition.

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

Patents have a limited lifespan. In the U.S., and most other jurisdictions in which we have undertaken patent filings, the natural expiration of a patent is generally twenty years after it is filed, assuming all maintenance fees are paid. Various extensions may be available, on a jurisdiction-by-jurisdiction basis; however, the life of a patent, and thus the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, patents we may own or in-license may not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing drugs similar or identical to our current or future product candidates, including generic versions of such drugs.

Depending upon the timing, duration and specifics of FDA marketing approval of our current or future product candidates, one or more of the U.S. patents we own or license may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. Different laws govern the extension of patents on approved pharmaceutical products in Europe and other jurisdictions. However, we may not be granted a patent 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. For example, we may not be granted an extension in the U.S. if all of our patents covering an approved product expire more than fourteen years from the date of NDA approval for a product covered by those patents. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our ability to generate revenues could be materially adversely affected.

If our trademarks and trade names for our products or company name are not adequately protected in one or more countries where we intend to market our products, we may delay the launch of product brand names, use different trademarks or tradenames in different countries, or face other potentially adverse consequences to building our product brand recognition.

We use and will continue to use registered and/or unregistered trademarks or trade names to brand and market ourselves and our products. Our trademarks or trade names may be challenged, infringed, diluted, circumvented or declared generic or determined to be infringing on other marks. We intend to rely on both registration and common law protection for our trademarks. 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. During the trademark registration process, we may receive Office Actions from the USPTO or from comparable agencies in foreign jurisdictions objecting to the registration of our trademark. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and/or to seek the cancellation of registered trademarks. Opposition or cancellation proceedings may be filed against our trademark applications or registrations, and our trademark applications or registrations may not survive such proceedings. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long run, if we are unable to obtain a registered trademark or 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.

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

If we are unable to adequately protect and enforce our trade secrets, our business and competitive position would be harmed.

In addition to the protection afforded by patents we may own or in-license, we seek to rely on trade secret protection, confidentiality agreements, and license agreements to protect proprietary know-how that may not be patentable, processes for which patents are difficult to enforce and any other elements of our product discovery and development processes that involve proprietary know-how, information, or technology that may not be covered by patents. Although we require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information, or technology to enter into non-disclosure and confidentiality agreements, trade secrets can be difficult to protect and we have limited control over the protection of trade secrets used by our collaborators and suppliers. We cannot be certain that we have or will obtain these agreements in all circumstances and we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary information.

Moreover, any of these parties might breach the agreements and intentionally or inadvertently disclose our trade secret information and we may not be able to obtain adequate remedies for such breaches. In addition, competitors may otherwise gain access (such as through a cybersecurity breach) to our trade secrets or independently develop substantially equivalent information and techniques. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. 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. Furthermore, the laws of some foreign countries do not protect proprietary rights and trade secrets to the same extent or in the same manner as the laws of the U.S. We may need to share our proprietary information, including trade secrets, with future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the U.S. and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, financial condition, results of operations and future prospects.

We may initiate, become a defendant in, or otherwise become party to lawsuits to protect or enforce our intellectual property rights, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe or otherwise violate any patents or other intellectual property we may own or in-license. In addition, any patents we may own or in-license also may become involved in inventorship, priority, validity or unenforceability disputes. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any such claims could provoke these parties to assert counterclaims against us, including claims alleging that we infringe their patents or other intellectual property rights. In patent litigation in the U.S. and in some other jurisdictions, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld material information from the USPTO or the applicable foreign counterpart, or made a misleading statement, during prosecution. A litigant or the USPTO itself could challenge our patents on this basis even if we believe that we have conducted our patent prosecution in accordance with the duty of candor and in good faith. The outcome following such a challenge is unpredictable. Moreover, with respect to challenges to the validity of our patents, there might be invalidating prior art, of which we and the patent examiner were unaware during prosecution.

We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, in an infringement proceeding, a court may decide that one or more of any patents we may own or in-license is not valid or is unenforceable or that the other party's use of our technology that may be patented falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1). There is also the risk that, even if the validity of these patents is upheld, the court may refuse to stop the other party from using the technology at issue on the grounds that any patents we may own or in-license do not cover the technology in question or that such third party's activities do not infringe our patent applications or any patents we may own or in-license. An adverse result in any litigation or defense proceedings could put one or more of any patents we may own or in-license at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, patient support or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

We may be required to protect our patents through procedures created to attack the validity of a patent at the USPTO. Post-grant proceedings, including post-grant review, *inter partes* review and derivation proceedings, provoked by third parties or brought by the USPTO may be necessary to determine the validity or priority of inventions with respect to our patent applications or any patents we may own or in-license. These proceedings are expensive and 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. In addition to potential USPTO post-grant proceedings, we may become a party to patent opposition proceedings in the EPO, or similar proceedings in other foreign patent offices or courts where our patents may be challenged. The costs of these proceedings could be substantial, and may result in a loss of scope of some claims or a loss of the entire patent. An unfavorable result in a post-grant challenge proceeding may result in the loss of our right to exclude others from practicing one or more of our inventions in the relevant country or jurisdiction, which could have a material adverse effect on our business. Litigation or post-grant proceedings within patent offices 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.

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.

We may not be able to detect infringement against any patents we may own or in-license. Even if we detect infringement by a third party of any patents we may own or in-license, we may choose not to pursue litigation against or settlement with the third party. If we 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 to enforce any patents we may own or in-license against such third party.

Intellectual property litigation and administrative patent office patent validity challenges in one or more countries could cause us to spend substantial resources and distract our personnel from their normal responsibilities. Even if resolved in our favor, 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. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace, including compromising our ability to raise the funds necessary to continue our preclinical studies and future clinical trials, continue our discovery programs, license necessary technology from third parties, or enter into development collaborations that would help us commercialize our current or future product candidates, if approved.

In addition, if our product candidates are found to infringe the intellectual property rights of third parties, these third parties may assert infringement claims against our licensees and other parties with whom we have business relationships, and we may be required to indemnify those parties for any damages they suffer as a result of these claims. The claims may require us to initiate or defend protracted and costly litigation on behalf of licensees and other parties regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of those parties or may be required to obtain licenses for the products they use.

Any of the foregoing events would harm our business, financial condition, results of operations and prospects.

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

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

Our current and future licensors may have relied on third-party consultants or collaborators or on funds from third parties, such as the U.S. government, such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights or other rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

In the case of employees, we enter into agreements providing 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. Although we require all of our employees to assign their inventions to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain. Defending against such law suits will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.

The intellectual property landscape relevant to our products and programs is crowded, and third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business. Our commercial success depends upon our ability to develop, manufacture, market and sell our current and future product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property 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 derivation, interference, reexamination, *inter partes* review and post grant review proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We or any of our current or future licensors or strategic partners may be party to, exposed to, or threatened with, future adversarial proceedings or litigation by third parties having patent or other intellectual property rights alleging that our current or future product candidates and/or proprietary technologies infringe, misappropriate or otherwise violate their intellectual property rights. We cannot assure you that our current or future product candidates, the QuEEN platform, and other technologies that we have developed, are developing or may develop in the future do not or will not infringe, misappropriate or otherwise violate existing or future patents or other intellectual property rights owned by third parties.

While certain activities related to development and preclinical and clinical testing of our current or future product candidates may be subject to safe harbor of patent infringement under 35 U.S.C. §271(e)(1), upon receiving FDA approval for such candidates we or any of our future licensors or strategic partners may immediately become party to, exposed to, or threatened with, future adversarial proceedings or litigation by third parties having patent or other intellectual property rights alleging that such product candidates infringe, misappropriate or otherwise violate 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 current or future product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our current or future 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 current or future product candidates, technologies or methods.

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

- infringement, misappropriation 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 and may impact our reputation;
- substantial damages for infringement, misappropriation or other violations, which we may have to pay if a court decides that the product candidate or technology at issue infringes, misappropriates 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 current or future product candidates, or from using our proprietary technologies, including our QuEEN platform, unless the third-party licenses its product rights to us, which it is not required to do on commercially reasonable terms or at all;
- 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, or the license to us may be non-exclusive, which would permit third parties to use the same intellectual property to compete with us;
- redesigning our current or future product candidates or processes so they do not infringe, misappropriate or violate third-party intellectual property rights, which may not be possible or may require substantial monetary expenditures and time; and
- 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.

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. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition, results of operations or prospects.

Third parties may assert that we are employing their proprietary technology without authorization. Patents issued in the U.S. by law enjoy a presumption of validity that can be rebutted in U.S. courts only with evidence that is “clear and convincing," a heightened standard of proof. There may be issued third-party patents of which we are currently unaware with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our current or future product candidates. Patent applications can take many years to issue. In addition, because some patent applications in the U.S. may be maintained in secrecy until the patents are issued, patent applications in the U.S. and many foreign jurisdictions are typically not published until 18 months after their earliest priority filing date, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications covering our current or future product candidates or technology. If any such patent applications issue as patents, and if such patents have priority over our patent applications or patents we may own or in-license, we may be required to obtain rights to such patents owned by third parties which may not be available on commercially reasonable terms or at all, or may only be available on a non-exclusive basis. There may be currently pending third-party patent applications which may later result in issued patents that our current or future product candidates may infringe. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our current or future product candidates or other technologies, could be found to be infringed by our current or future product candidates or other technologies. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Moreover, we may fail to identify relevant patents or incorrectly conclude that a patent is invalid, not enforceable, exhausted, or not infringed by our activities. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our current or future product candidates, 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, including combination therapy or patient selection methods, 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 current or future product candidates or the QuEEN platform may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be nonexclusive, thereby giving our competitors access to the same technologies licensed to us.

In addition, 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 current or future product candidates. Defense of these claims, regardless of their merit, could 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, misappropriation or other violation 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, 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 or may choose to obtain licenses from third parties to advance our research or allow commercialization of our current or future product candidates, which licenses may not be available on commercially reasonable terms, or at all. In that event, we would be unable to further develop and commercialize our current or future product candidates or technologies, which could harm our business significantly.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information or alleged trade secrets of third parties or competitors or are in breach of non-competition or non-solicitation agreements with our competitors or their former employers.

As is common in the biotechnology and pharmaceutical industries, we employ individuals and engage the services of consultants who previously worked for other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending and we try to ensure that our employees, consultants and advisors 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 these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's former employer. We may also be subject to claims that patents and applications we have filed to protect inventions of our employees, consultants and advisors, even those related to one or more of our current or future product candidates, the QuEEN platform, or other technologies, are rightfully owned by their former or concurrent employer. 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.

We will not obtain patent or other intellectual property protection for any current or future product candidates in all jurisdictions throughout the world, and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

We may not be able to pursue patent coverage of our current or future product candidates, the QuEEN platform, or other technologies in all countries. Filing, prosecuting and defending patents on current or future product candidates, the QuEEN platform, and other technologies in all countries throughout the world would be prohibitively expensive, and 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 infringing on 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 current or future product candidates and in jurisdictions where we do not have any issued patents our patent applications or other intellectual property rights may not be effective or sufficient to prevent them from competing. Much of our patent portfolio is at the very early stage. We will need to decide whether and in which jurisdictions to pursue protection for the various inventions in our portfolio prior to applicable deadlines.

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 pharmaceutical products, which could make it difficult for us to stop the infringement of any patents we may own or in-license or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce any rights we may have in our patent applications or any patents we may own or in-license in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put any patents we may own or in-license 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.

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

We may not obtain or grant licenses or sublicenses to intellectual property rights in all markets on equally or sufficiently favorable terms with third parties.

It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties. The licensing of third-party intellectual property rights is a competitive area, and more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. More established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to license such technology, or if we are forced to license such technology on unfavorable terms, our business could be materially harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected current or future product candidates, which could materially harm our business, and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation. 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. Any of the foregoing could harm our competitive position, business, financial condition, results of operations and prospects.

Further, our licensors may retain certain rights under their agreements with us, including the right to use the underlying technology for noncommercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse. In addition, the United States federal government retains certain rights in inventions produced with its financial assistance under the Patent and Trademark Law Amendments Act, or the Bayh-Dole Act. The federal government retains a “nonexclusive, nontransferable, irrevocable, paid-up license” for its own benefit. The Bayh-Dole Act also provides federal agencies with “march-in rights.” March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a “nonexclusive, partially exclusive, or exclusive license” to a “responsible applicant or applicants.” If the patent owner refuses to do so, the government may grant the license itself. If, in the future, we co-own or license in technology which is critical to our business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected.

If we fail to comply with our obligations in our current or any future agreements under which we may license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We are dependent on patents, know-how and proprietary technology, both our own and in-licensed from collaborators. We may in the future enter into more license agreements with third parties under which we receive rights to intellectual property that are important to our business. Our commercial success depends upon our ability to develop, manufacture, market and sell our current or future product candidates and use our and our licensors’ proprietary technologies without infringing the proprietary rights of third parties. Our success will also depend in part on the ability of our licensors to obtain, maintain and enforce patent protection for our licensed intellectual property, in particular, those patents to which we have secured exclusive rights. Our licensors may not successfully prosecute the patent applications to which we are licensed. Even if patents are issued in respect of these patent applications, our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents, or may pursue such litigation less aggressively than we would. Without protection for the intellectual property we license, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business prospects. Further, we may have limited control over these activities or any other intellectual property that may be in-licensed. For example, we cannot be certain that such activities by 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. In the event our licensors fail to adequately pursue and maintain patent protection for patents and applications they control, and to timely cede control of such prosecution to us, our competitors might be able to enter the market, which would have a material adverse effect on our business.

In addition, our current and future intellectual property license agreements may require us various development, regulatory and/or commercial diligence obligations, payment of milestones and/or royalties and other obligations. If we fail to comply with our obligations under these agreements (including as a result of COVID-19 impacting our operations), we use the licensed intellectual property in an unauthorized manner or we are subject to bankruptcy-related proceedings, the terms of the licenses may be materially modified, such as by rendering currently exclusive licenses non-exclusive, or it may give our licensors the right to terminate their respective agreement with us. Any termination of these licenses, or if the underlying patents fail to provide the intended exclusivity, could result in the loss of significant rights and could harm our ability to commercialize our current or future product candidates, the QuEEN platform, or other technologies, competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical to ours, and we may be required to cease our development and commercialization of certain of our current or future product candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Disputes may also arise between us and our current or future 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, misappropriate or otherwise violate intellectual property rights 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;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our current or future product candidates, and what activities satisfy those diligence obligations;
- our right to transfer or assign the license;

- the priority of invention of any patented technology; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our current or future licensors and us and our partners.

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

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

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 16, 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. On March 16, 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO on or after March 16, 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our or our licensor’s patents or patent applications.

The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the enforcement or defense of our owned or in-licensed issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, the patent positions of companies in the development and commercialization of biopharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might subject us to infringement claims or adversely affect our ability to develop and market our current or future product candidates.

We cannot guarantee that any of our or our licensors’ patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending patent application in the U.S. and abroad that is relevant to or necessary for the commercialization of our current or future product candidates in any jurisdiction. For example, U.S. patent applications filed before November 29, 2000 and certain U.S. patent applications filed after that date that will not be filed outside the U.S. remain confidential until patents issue. As mentioned above, patent applications in the U.S. and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our current or future product candidates could have been filed by third parties without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our current or future product candidates or the use of our current or future product candidates. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our current or future product candidates. We may incorrectly determine that our current or future product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the U.S. or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our current or future product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our current or future product candidates.

If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, which may be significant, we may be temporarily or permanently prohibited from commercializing any of our current or future product candidates or technologies that are held to be infringing. We might, if possible, also be forced to redesign current or future product candidates so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business and could adversely affect our business, financial condition, results of operations and prospects.

Intellectual property rights do not guarantee commercial success of current or future product candidates or other business activities. Numerous factors may limit any potential competitive advantage provided by our intellectual property rights.

The degree of future protection afforded by our intellectual property rights, whether owned or in-licensed, is uncertain because intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors, or permit us to maintain our competitive advantage. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The following examples are illustrative:

- patent applications that we own or may in-license may not lead to issued patents;
- patents, should they issue, that we may own or in-license, may not provide us with any competitive advantages, may be narrowed in scope, or may be challenged and held invalid or unenforceable;
- others may be able to develop and/or practice technology, including compounds that are similar to the chemical compositions of our current or future product candidates, that is similar to our technology or aspects of our technology but that is not covered by the claims of any patents we may own or in-license, should any patents issue;
- third parties may compete with us in jurisdictions where we do not pursue and obtain patent protection;
- we, or our future licensors or collaborators, might not have been the first to make the inventions covered by a patent application that we own or may in-license;
- we, or our future licensors or collaborators, might not have been the first to file patent applications covering a particular invention;
- others may independently develop similar or alternative technologies without infringing, misappropriating or otherwise violating our intellectual property rights;
- our competitors might conduct research and development activities in the U.S. and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and may then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not be able to obtain and/or maintain necessary licenses on reasonable terms or at all;
- third parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights, or any rights at all, over that intellectual property;

- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such trade secrets or know-how;
- we may not be able to maintain the confidentiality of our trade secrets or other proprietary information;
- we may not develop or in-license additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

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

Risks related to employee matters, managing growth and other risks related to our business

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the research and development, clinical and business development expertise of Markus Warmuth, M.D., our Chief Executive Officer, Owen Wallace, Ph.D., our Chief Scientific Officer, John Castle, Ph.D., our Chief Data Scientist, Sharon Townson, our Chief Technology Officer, Filip Janku, our Chief Medical Officer and Ajim Tamboli, our Chief Financial Officer, as well as the other principal members of our management and scientific teams. Although we have entered into employment letter agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize drugs. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Failure to succeed in clinical trials may make it more challenging to recruit and retain qualified scientific personnel. In addition, in order to induce employees to continue their employment with us, we have provided equity awards that vest over time and the value to our employees of such equity awards may be significantly affected by movements in our stock price that are beyond our control and may be at any time insufficient to counteract more lucrative offers from other companies. If we are unable to continue to attract and retain high quality personnel, the rate and success at which we can develop and commercialize product candidates will be limited.

We will need to develop and expand our company, and we may encounter difficulties in managing this development and expansion, which could disrupt our operations.

As of November 9, 2021, we had 94 full-time employees. We expect to increase our number of employees and the scope of our operations, including the areas of data sciences, platform biology and chemistry, drug discovery, clinical development, finance, business development, and legal. To manage our anticipated development and expansion, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Our management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these development activities. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the development of our current or future product candidates. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our current or future product candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage the future development and expansion of our company.

We have offices in multiple countries and we may further expand in the future, which presents challenges in managing our business operations.

We are headquartered in Boston, Massachusetts and have offices in Basel, Switzerland. Conducting our business in multiple countries subjects us to a variety of risks and complexities that may materially and adversely affect our business, results of operations, financial condition and growth prospects, including, among other things:

- the increased complexity and costs inherent in managing international operations;
- diverse regulatory, financial and legal requirements, and any future changes to such requirements, in one or more countries where we are located or do business;
- country-specific tax, labor and employment laws and regulations;
- challenges inherent in efficiently managing employees in diverse geographies, including the need to adapt systems, policies, benefits and compliance programs to differing labor and other regulations;
- liabilities for activities of, or related to, our international operations or product candidates;
- changes in currency rates; and
- regulations relating to data security and the unauthorized use of, or access to, commercial and personal information.

We continue to expand our operations, and our corporate structure and tax structure is complex. In connection with our current and future potential partnerships, we are actively engaged in developing and applying technologies and intellectual property with a view toward commercialization of products globally, often with commercialization partners. In connection with those activities, we already have and will likely continue to engage in complex cross-border and global transactions involving our technology, intellectual property and other assets, between us and other entities such as partners and licensees, and between us and our subsidiaries. Such cross-border and global arrangements are both difficult to manage and can potentially give rise to complexities in areas such as tax treatment, particularly since we are subject to multiple tax regimes and different tax authorities can also take different views from each other, even as regards the same cross-border transaction or arrangement. There can be no assurance that we will effectively manage this increased complexity without experiencing operating inefficiencies, control deficiencies or tax liabilities. Significant management time and effort is required to effectively manage the increased complexity of our company, and our failure to successfully do so could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We or the third parties upon whom we depend may be adversely affected by natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Natural disasters could severely disrupt our operations and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities on which we rely, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place 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. For example, following Hurricane Maria, shortages in production and delays in a number of medical supplies produced in Puerto Rico resulted, and any similar interruption due to a natural disaster affecting us or any of our third-party manufacturers could materially delay our operations.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

As widely reported, global credit and financial markets have experienced extreme volatility and disruptions in the past several years, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability, including most recently in connection with the COVID-19 pandemic. There can be no assurance that further volatility in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets continue to be volatile it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Furthermore, our stock price may decline due in part to the volatility of the stock market and a general economic downturn.

Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay, scale back or discontinue the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics, pandemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

Our internal computer systems, or those of our third-party CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our current or future product candidates' development programs.

Despite the implementation of security measures, our internal computer systems and those of our third-party CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such system failure, accident, 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 programs. For example, the loss of data from preclinical studies or future clinical trials for our current or future product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, other data or applications relating to our technology or current or future product candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the further development of our current or future product candidates could be delayed.

We may be unable to adequately protect our information systems from cyberattacks, which could result in the disclosure of confidential or proprietary information, including personal data, damage our reputation, and subject us to significant financial and legal exposure.

We rely on information technology systems that we or our third-party providers operate to process, transmit and store electronic information in our day-to-day operations. In connection with our product discovery efforts, we may collect and use a variety of personal data, such as name, mailing address, email addresses, phone number and clinical trial information. A successful cyberattack could result in the theft or destruction of intellectual property, data or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. Cyberattacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyberattacks could include wrongful conduct by hostile foreign governments, industrial espionage, wire fraud and other forms of cyber fraud, the deployment of harmful malware, denial-of-service, social engineering fraud or other means to threaten data security, confidentiality, integrity and availability. A successful cyberattack could cause serious negative consequences for us, including, without limitation, the disruption of operations, the misappropriation of confidential business information, including financial information, trade secrets, financial loss and the disclosure of corporate strategic plans. Although we devote resources to protect our information systems, we realize that cyberattacks are a threat, and there can be no assurance that our efforts will prevent information security breaches that would result in business, legal, financial or reputational harm to us, or would have a material adverse effect on our results of operations and financial condition. Any failure to prevent or mitigate security breaches or improper access to, use of, or disclosure of our clinical data or patients' personal data could result in significant liability under state (*e.g.*, state breach notification laws), federal (*e.g.*, HIPAA, as amended by HITECH), and international law (*e.g.*, the EU General Data Protection Regulation, or GDPR) and may cause a material adverse impact to our reputation, affect our ability to use collected data, conduct new studies and potentially disrupt our business.

We rely on our third-party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. We also rely on our employees and consultants to safeguard their security credentials and follow our policies and procedures regarding use and access of computers and other devices that may contain our sensitive information. If we or our third-party providers fail to maintain or protect our information technology systems and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to our information technology systems, we or our third-party providers could have difficulty preventing, detecting and controlling such cyber-attacks and any such attacks could result in losses described above, as well as disputes with physicians, patients and our partners, regulatory sanctions or penalties, increases in operating expenses, expenses or lost revenues or other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects and cash flows. Any failure by such third parties to prevent or mitigate security breaches or improper access to or disclosure of such information could have similarly adverse consequences for us. If we are unable to prevent or mitigate the impact of such security or data privacy breaches, we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to our business.

Our employees, principal investigators, CROs and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading laws.

We are exposed to the risk that our employees, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate the regulations of the FDA and other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities; healthcare fraud and abuse laws and regulations in the U.S. and abroad; or laws that require the reporting of financial information or data accurately. In particular, sales, marketing, patient support and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Other activities subject to these laws include the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant criminal, civil and administrative sanctions including monetary penalties, damages, fines, disgorgement, individual imprisonment, reputational harm, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management’s attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes to offset future taxable income may be subject to certain limitations.

As of December 31, 2020, we had federal and state net operating loss carryforwards of $2.8 million and $2.8 million, respectively, which begin to expire in various amounts in 2039 (other than federal net operating loss carryforwards arising in taxable years beginning after December 31, 2019, which are not subject to expiration). As of December 31, 2020, we had foreign net operating loss carryforwards of $38.5 million that expire in 2026. As of December 31, 2020, we also had federal and state research and development tax credit carryforwards of $0.3 million and $0.1 million, respectively, which begin to expire in 2034. These net operating loss and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. In addition, in general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its pre-change net operating losses or tax credits, or NOLs or credits, to offset future taxable income or taxes. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders or groups of stockholders who owns at least 5% of a corporation’s stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a specified testing period.

Future changes in our stock ownership, many of which are outside of our control, could result in an ownership change under Sections 382 and 383 of the Code. Our NOLs or credits may also be impaired under state law. Accordingly, we may not be able to utilize a material portion of our NOLs or credits.

Furthermore, our ability to utilize our NOLs or credits is conditioned upon our attaining profitability and generating U. S. federal and state taxable income. As described above under “Risk factors—Risks related to our financial position and capital needs,” we have incurred significant net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future; and therefore, we do not know whether or when we will generate the U.S. federal or state taxable income necessary to utilize our NOL or credit carryforwards that are subject to limitation by Sections 382 and 383 of the Code.

Changes in tax law may adversely affect us or our investors.

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, or IRS, 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 changes have been made and changes are likely to continue to occur in the future.

It cannot be predicted whether, when, in what form, or with what effective dates, new tax laws may be enacted, or regulations and rulings may be enacted, promulgated or issued under existing or new tax laws, which could result in an increase in our or our shareholders’ tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law or in the interpretation thereof.

Risks related to our common stock

The price of our common stock may be volatile and fluctuate substantially, and you could lose all or part of your investment.

Our stock price is likely to be volatile. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above the price you paid for your common stock. The market price for our common stock may be influenced by many factors, including:

- the success of competitive drugs or technologies;
- results of preclinical studies and clinical trials of our current or future product candidates or those of our competitors;
- unanticipated safety concerns related to the use of any of our product candidates;
- regulatory or legal developments in the U.S. and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our current or future product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional current or future product candidates or drugs;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- product liability claims or other litigation;
- changes in the structure of healthcare payment systems;

- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this “Risk factors” section.

The stock market in general, and the Nasdaq Global Select Market and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies, including very recently in connection with the ongoing COVID-19 pandemic, which has resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. Broad market and industry factors, including potentially worsening economic conditions and other adverse effects or developments relating to the ongoing COVID-19 pandemic, may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this section, could have a significant and material adverse impact on the market price of our common stock.

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

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of private and public equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. We do not currently have any committed external source of funds. 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, and the terms of these securities may include liquidation or other preferences that materially adversely affect your rights as a common stockholder. Debt financing, if available, would increase our fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise funds through additional collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, future revenue streams, discovery programs or current or future product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, scale back or discontinue the development and commercialization of one or more of our product candidates, delay our pursuit of potential in-licenses or acquisitions or grant rights to develop and market current or future product candidates that we would otherwise prefer to develop and market ourselves.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock will rely in part on the research and reports that industry or financial analysts publish about us or our business. We do not have any control over the analysts or the content and opinions included in their reports. If we receive negative evaluations of our stock by industry or financial analysts, the price of our stock could decline.

We have identified material weaknesses in our internal control over financial reporting. If we are unable to successfully remediate these material weaknesses in our internal control over financial reporting, it could have an adverse effect on our company.

We have identified material weaknesses in our internal control over financial reporting for the years ended December 31, 2020 and 2019. The material weaknesses we identified were (i) we did not maintain an effective control environment as we did not maintain a sufficient complement of accounting and financial reporting resources commensurate with our financial reporting requirements, (ii) we did not maintain an effective risk assessment process, which led to improperly designed controls, (iii) we did not maintain appropriate control activities to support the appropriate segregation of duties over the review of account reconciliations and manual journal entries, and (iv) we did not document, thoroughly communicate and monitor controls processes and relevant accounting policies and procedures. These material weaknesses could result in a misstatement of account balances or disclosures that would result in a material misstatement to the annual or interim financial statements that would not be prevented or detected. Had we performed an evaluation of our internal control over financial reporting in accordance with Section 404, additional control deficiencies may have been identified by management, and those control deficiencies could have also represented one or more material weaknesses.

In an effort to remediate the material weaknesses, we have retained an accounting consulting firm to provide additional depth and breadth in our technical accounting and financial reporting capabilities. We have also hired additional qualified accounting and finance personnel to provide needed levels of expertise in our internal accounting function and maintain appropriate segregation of duties. [We intend to complete an appropriate risk assessment to identify relevant risks and specify needed objectives. We intend to formalize and communicate our policies and procedures surrounding our financial close, financial reporting and other accounting processes. We intend to further develop and document necessary policies and procedures regarding our internal control over financial reporting, such that we are able to perform a Section 404 analysis of our internal control over financial reporting when and as required.] We cannot assure you that these measures will significantly improve or remediate the material weaknesses described above. We also cannot assure you that we have identified all or that we will not have additional material weaknesses in the future. Accordingly, a material weakness may still exist when we report on the effectiveness of our internal control over financial reporting for purposes of our attestation when required by reporting requirements under the Exchange Act or Section 404 in the future. Further, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm.

We expect to incur additional costs to remediate these control deficiencies, though there can be no assurance that our efforts will be successful or avoid potential future material weaknesses. If we are unable to successfully remediate our existing or any future material weaknesses in our internal control over financial reporting, or if we identify any additional material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, investors may lose confidence in our financial reporting, and our stock price may decline as a result. We also could become subject to investigations by Nasdaq, the SEC or other regulatory authorities.

Our executive officers, directors, principal stockholders and their affiliates own a significant percentage of our stock and are able to exercise significant influence over our company, which will limit your ability to influence corporate matters and could delay or prevent a change in corporate control.

Based on our common stock outstanding as of September 30, 2021, our executive officers, directors, principal stockholders and their affiliates beneficially owned, in the aggregate, of a majority of our outstanding common stock. In addition, six of our directors, including our chief executive officer, are affiliated with our principal stockholders. As a result, these stockholders, if they act together, will be able to influence our management and affairs and the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. The concentration of voting power among these stockholders may have an adverse effect on the price of our common stock. In addition, this concentration of ownership might adversely affect the market price of our common stock by:

- delaying, deferring or preventing a change of control of us;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to compliance initiatives applicable to public companies.

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which requires, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act of 2002, as amended, or Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and The Nasdaq Stock Market LLC to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas, such as “say on pay” and proxy access. Emerging growth companies may implement many of these requirements over a longer period and up to five years from the pricing of their initial public offering. We intend to take advantage of these extended transition periods, but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will decrease our net income or increase our net loss and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

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 fourth 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 board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office;
- 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 preferred stock on terms determined by the board of directors without stockholder approval and which 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 Corporate Law, or DGCL, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These antitakeover provisions and other provisions in our fourth 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.

Our amended and restated bylaws designate specific courts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit stockholders' ability to obtain a favorable judicial forum for disputes with us.

Pursuant to our amended and restated bylaws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for any state law claims for (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of or based on a breach of a fiduciary duty owed by any director, officer or other employee of ours to us or our stockholders; (iii) any action asserting a claim pursuant to any provision of the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws; or (iv) any action asserting a claim governed by the internal affairs doctrine, or the Delaware Forum Provision. The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act of 1933, as amended, or the Securities Act or the Securities Exchange Act of 1934, as amended, or the Exchange Act. Our amended and restated bylaws further provide that unless we consent in writing to the selection of an alternative forum, the United States District Court for the District of Massachusetts shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or the Federal Forum Provision. In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have notice of and consented to the Delaware Forum Provision and the Federal Forum

Provision; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

We recognize that the Delaware Forum Provision and the Federal Forum Provision in our amended and restated bylaws may impose additional litigation costs on stockholders in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware or the Commonwealth of Massachusetts, as applicable. Additionally, the forum selection clauses in our amended and restated bylaws may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage the filing of lawsuits against us and our directors, officers and employees, even though an action, if successful, might benefit our stockholders. In addition, 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 Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the United States District Court for the District of Massachusetts may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

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

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline.

In addition, shares of common stock that are either subject to outstanding options, reserved for future issuance under our equity incentive plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, Rule 144 and Rule 701 under the Securities Act and other legal restrictions. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

We have broad discretion in how we use our existing cash and cash equivalents and may not use them effectively, which could affect our results of operations and cause our stock price to decline.

We will have considerable discretion in the application of our existing cash and cash equivalents (including our net proceeds from our initial public offering), and you will not have the opportunity as part of your investment decision to assess whether our existing cash and cash equivalents are being used appropriately. As a result, investors will be relying upon management's judgment with only limited information about our specific intentions for the use of the balance of our existing cash and cash equivalents. We may use the our existing cash and cash equivalents for purposes that do not yield a significant return or any return at all for our stockholders. In addition, pending their use, we may invest our existing cash and cash equivalents in a manner that does not produce income or that loses value.

If we fail to establish and maintain proper and effective internal control over financial reporting, our operating results and our ability to operate our business could be harmed.

Adequate internal control over financial reporting are necessary for us to provide reliable financial reports and, together with effective disclosure controls and procedures, are designed to prevent or detect material misstatements. Adequate internal control over financial reporting are necessary for us to provide reliable financial reports and, together with effective disclosure controls and procedures, are designed to prevent or detect material misstatements. Implementing any appropriate changes to our internal controls may distract our officers and employees, entail substantial costs to modify our existing processes, and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and harm our business. In addition, investors' perceptions that our internal controls are inadequate or that we are unable to produce accurate financial statements on a timely basis may harm our stock price and make it more difficult for us to effectively market and sell any of our present or future product candidates that may receive regulatory approval.

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

Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

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 companies and smaller reporting companies will make our common stock less attractive to investors.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act, or 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, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act reduced disclosure obligations regarding executive compensation in this Quarterly Report and our periodic reports and proxy statements, and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years following the year in which we completed our initial public offering, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of the closing of our initial public offering, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) 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 prior June 30th, and (ii) the date on which we have issued more than $1 billion in non-convertible debt during the prior three-year period.

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 elected to not “opt out” of this exemption from complying with new or revised accounting standards and, therefore, we will adopt new or revised accounting standards at the time private companies adopt the new or revised accounting standard and will do so until such time that we either (i) irrevocably elect to “opt out” of such extended transition period or (ii) no longer qualify as an emerging growth company.

Even after we no longer qualify as an emerging growth company, we may still qualify as a “smaller reporting company,” which would allow us to continue to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in this Quarterly Report and our periodic reports and proxy statements. 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.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

If our estimates or judgments relating to our critical accounting policies are based on assumptions that change or prove to be incorrect, our operating results could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and accompanying notes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets, liabilities, equity, revenue and expenses that are not readily apparent from other sources. If our assumptions change or if actual circumstances differ from our assumptions, our operating results may be adversely affected and could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

Item 2. Unregistered sales of equity securities and use of proceeds

Set forth below is information regarding shares of equity securities sold, and options granted, by us during the nine months ended September 30, 2021 that were not registered under the Securities Act.

Recent Sales of Unregistered Equity Securities

On June 28, 2021, upon the closing of our initial public offering, or IPO, all 109,686,035 shares of our then-outstanding redeemable convertible preferred stock automatically converted into 31,068,102 shares of our common stock. The issuance of such common stock was exempt from the registration requirements of the Securities Act, pursuant to Section 3(a)(9) of the Securities Act, involving an exchange of securities exchanged by the issuer with its existing security holders exclusively where no commission or other remuneration is paid or given directly or indirectly for soliciting such exchange. No underwriters were involved in this issuance of shares.

During the period between January 1, 2021 and September 30, 2021, we issued to certain of our employees, advisors and directors, options to purchase an aggregate of 3,812,300 shares of our common stock at an average exercise price of $10.14 per share. We deemed these issuances to be exempt from registration under the Securities Act in reliance on Rule 701 of the Securities Act as sales and offers under compensatory benefit or Section 4(a)(2) of the Securities Act as sales and offers not involving a public offering

Use of Proceeds from IPO of Common Stock

On June 28, 2021, we completed the IPO of our common stock pursuant to which we issued and sold 11,700,000 shares of our common stock at a public offering price of $19.00 per share. On July 23, 2021, the underwriters of the Company's IPO exercised their option to purchase additional shares in full and the Company issued 1,755,000 of our common stock at the price of $19.00 per share.

The offer and sale of all of the shares of our common stock in our IPO were registered under the Securities Act pursuant to a registration statement on Form S-1, as amended (File No. 333- 256773), which was declared effective by the SEC on June 23, 2021. J.P. Morgan Securities LLC, Cowen and Company, LLC, Piper Sandler & Co. and Guggenheim Securities, LLC acted as underwriters for the IPO.

We received aggregate gross proceeds from our IPO of $255.6 million, or aggregate net proceeds of $234.8 million after deducting underwriting discounts and commissions and other offering costs. None of the underwriting discounts and commissions or offering expenses were incurred or paid, directly or indirectly, to any of our directors or officers or their associates or to persons owning 10% or more of our common stock or to any of our affiliates.

There has been no material change in our planned use of the net proceeds from the IPO as described in our final prospectus dated June 25, 2021.

Item 3. Defaults upon senior securities

None

Item 4. Mine safety disclosures

Not Applicable

Item 6. Exhibits

Exhibit Number	Description
3.1	Fourth Amended and Restated Certificate of Incorporation of the Registrant, as currently in effect (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K (File No. 001-40522))
3.2	Amended and Restated By-laws of the Registrant, as currently in effect (incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K (File No. 001-40522))
4.1	Form of Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.2 of the Registrant's Registration Statement on Form S-1, as amended (File No. 333-256773))
10.1#	2021 Stock Option and Incentive Plan and forms of award agreements thereunder (incorporated by reference to Exhibit 99.2 of the Registrant's Registration Statement on Form S-8 (File No. 333-257406) filed on June 25, 2021)
10.2#	2021 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.3 of the Registrant's Registration Statement on Form S-1 (File No. 333-256773) filed on June 21, 2021)
10.3#	Employment Agreement between the Registrant and Markus Warmuth, effective as of June 28, 2021 (incorporated by reference to Exhibit 10.7 of the Registrant's Registration Statement on Form S-1, as amended (File No. 333-256773))
10.4#	Employment Agreement between the Registrant and Ajim Tamboli, effective as of June 28, 2021 (incorporated by reference to Exhibit 10.8 of the Registrant's Registration Statement on Form S-1, as amended (File No. 333-256773))
10.5#	Employment Agreement between the Registrant and Owen Wallace, effective as of June 28, 2021 (incorporated by reference to Exhibit 10.9 of the Registrant's Registration Statement on Form S-1, as amended (File No. 333-256773))
10.6#	Employment Agreement between the Registrant and Sharon Townson, effective as of June 28, 2021 (incorporated by reference to Exhibit 10.10 of the Registrant's Registration Statement on Form S-1, as amended (File No. 333-256773))
10.7#	Employment Agreement between the Registrant and John Castle, effective as of June 28, 2021 (incorporated by reference to Exhibit 10.11 of the Registrant's Registration Statement on Form S-1, as amended (File No. 333-256773))
10.8#	Employment Agreement between the Registrant and Filip Janku, effective as of June 28, 2021 (incorporated by reference to Exhibit 10.12 of the Registrant's Registration Statement on Form S-1, as amended (File No. 333-256773))
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of 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	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

Management contract or compensatory plan, contract, or arrangement.

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.

Company Name

Date: November 10, 2021

By: /s/ Markus Warmuth

Markus Warmuth
Chief Executive Officer
(**Principal Executive Officer)**

Date: November 10, 2021

By: /s/ Ajim Tamboli

Ajim Tamboli
Chief Financial Officer
(Principal Financial Officer)

Exhibit 31.1

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

I, Markus Warmuth, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ending September 30, 2021 of Monte Rosa Therapeutics, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: November 10, 2021

By: /s/ Markus Warmuth
Markus Warmuth
Chief Executive Officer

Exhibit 31.2

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

I, Ajim Tamboli, certify that:

1. I have reviewed this Quarterly Report of Form 10-Q for the period ending September 30, 2021 of Monte Rosa Therapeutics, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: November 10, 2021	By: /s/ Ajim Tamboli
	Ajim Tamboli
	Chief 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 of Monte Rosa Therapeutics, Inc. (the “Company”) on Form 10-Q for the period ending September 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: November 10, 2021

By: /s/ Markus Warmuth
Markus Warmuth
Chief Executive Officer

Exhibit 32.2

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 of Monte Rosa Therapeutics, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: November 10, 2021	By: /s/ Ajim Tamboli
	Ajim Tamboli
	Chief Financial Officer