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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2022

OR

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

For the transition period from _____ to _____

Commission File Number: 001-40794

DICE THERAPEUTICS, INC.

Delaware	**47-2286244**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
400 East Jamie Court, Suite 300 South San Francisco, California	**94080**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 566-1420

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	DICE	The Nasdaq Stock Market LLC

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

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

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

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

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

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

As of May 6, 2022, the registrant had 38,229,275 shares of common stock, $0.0001 par value per share, outstanding.

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This Quarterly Report on Form 10-Q, or Quarterly Report, contains forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “believe,” “may,” “will,” “potentially,” “estimate,” “continue,” “anticipate,” “intend,” “could,” “would,” “project,” “plan,” “expect,” “predict,” “potential” and similar expressions that convey uncertainty of future events or outcomes, although not all forward-looking statements contain these words. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in “Risk factors” and elsewhere in this filing. Moreover, we operate in a competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Quarterly Report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. The forward-looking statements in this Quarterly Report include, among other things, statements about:

- our ability to obtain funding for our operations, including funding necessary to complete the development and commercialization of our therapeutic candidates;
- the timing of and our ability to obtain and maintain regulatory approvals for our therapeutic candidates;
- future agreements with third parties in connection with the commercialization of our therapeutic candidates;
- the success, cost and timing of our therapeutic candidate development activities and planned clinical trials;
- our expectations regarding the impact of the COVID-19 pandemic and its potentially material adverse impact on our business, the macroeconomy, and the execution of our preclinical studies and clinical trials;
- the rate and degree of market acceptance and clinical utility of our therapeutic candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- the success of competing therapies that are or may become available;
- our ability to attract and retain key management and technical personnel;
- our expectations regarding our ability to obtain, maintain and enforce intellectual property protection for our therapeutic candidates;
- our use of our existing cash, cash equivalents, and marketable securities; and
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing.

The forward-looking statements made in this filing relate only to events or information as of the date on which the statements are made in this Quarterly Report. You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Quarterly Report to conform these statements to actual results or to changes in our expectations, except as required by law. We intend the forward-looking statements contained in this Quarterly Report to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”).

PART I: FINANCIAL INFORMATION

Item 1. Financial Statements

DICE THERAPEUTICS, INC.
Condensed Consolidated Balance Sheets
(Unaudited)
(In thousands, except share and per share amounts)

	March 31, 2022	December 31, 2021
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 53,668	$ 115,826
Marketable securities	249,563	203,495
Unbilled receivable	2,000	2,000
Restricted cash, current	150	150
Prepaid expenses and other current assets	1,615	2,440
Total current assets	306,996	323,911
Property and equipment, net	3,088	1,645
Restricted cash	198	198
Operating lease right-of-use assets	14,327	—
TOTAL ASSETS	$ 324,609	$ 325,754
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 4,753	$ 1,710
Accrued expenses and other current liabilities	8,154	8,691
Operating lease liabilities, current portion	1,173	—
Term loan, current portion	714	480
Total current liabilities	14,794	10,881
Operating lease liabilities, noncurrent	12,936	—
Other noncurrent liabilities	—	8
Term loan, noncurrent	1,710	1,916
TOTAL LIABILITIES	29,440	12,805
STOCKHOLDERS' EQUITY		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized, and no shares issued and outstanding as of March 31, 2022 and December 31, 2021	—	—
Common stock, $0.0001 par value; 500,000,000 shares authorized, 38,229,275 and 38,224,299 shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively	4	4
Additional paid-in capital	418,603	416,710
Accumulated deficit	(122,298)	(103,707)
Accumulated other comprehensive loss	(1,140)	(58)
TOTAL STOCKHOLDERS' EQUITY	295,169	312,949
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 324,609	$ 325,754

See accompanying notes.

DICE THERAPEUTICS, INC.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2022	**2021**
Operating expenses:		
Research and development	$ 13,410	$ 6,621
General and administrative	5,448	1,465
Total operating expenses	18,858	8,086
Loss from operations	(18,858)	(8,086)
Other income (expense):		
Interest and other income, net	327	14
Interest expense	(60)	(2)
Change in fair value of warrant liability	—	8
Net loss	(18,591)	(8,066)
Other comprehensive loss:		
Unrealized loss on marketable securities	(1,082)	(7)
Comprehensive loss	$ (19,673)	$ (8,073)
Net loss per share, basic and diluted	$ (0.50)	$ (3.59)
Weighted-average shares used in computing net loss per share, basic and diluted	37,261,685	2,248,687

See accompanying notes.

DICE THERAPEUTICS, INC.
Condensed Consolidated Statements of Convertible Preferred Units and Stockholders' Equity/Members' Deficit
(Unaudited)
(In thousands, except member unit data and share amounts)

	Convertible Preferred Units		Common Units		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Units	Cost	Units	Cost	Shares	Amount				
Balances as of December 31, 2021	—	$ —	—	$ —	38,224,299	$ 4	$ 416,710	$ (103,707)	$ (58)	$ 312,949
Issuance of common stock upon exercise of stock options	—	—	—	—	4,976	—	84	—	—	84
Stock-based compensation	—	—	—	—	—	—	1,809	—	—	1,809
Other comprehensive loss	—	—	—	—	—	—	—	—	(1,082)	(1,082)
Net loss	—	—	—	—	—	—	—	(18,591)	—	(18,591)
Balances as of March 31, 2022	—	$ —	—	$ —	38,229,275	$ 4	$ 418,603	$ (122,298)	$ (1,140)	$ 295,169

	Convertible Preferred Units		Common Units		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Members' Deficit
	Units	Cost	Units	Cost	Shares	Amount				
Balances as of December 31, 2020	12,690,540	$ 107,374	2,248,687	$ —	—	$ —	$ 1,603	$ (54,748)	$ —	$ (53,145)
Stock-based compensation	—	—	—	—	—	—	347	—	—	347
Other comprehensive loss	—	—	—	—	—	—	—	—	(7)	(7)
Net loss	—	—	—	—	—	—	—	(8,066)	—	(8,066)
Balances as of March 31, 2021	12,690,540	$ 107,374	2,248,687	$ —	—	$ —	$ 1,950	$ (62,814)	$ (7)	$ (60,871)

See accompanying notes.

DICE THERAPEUTICS, INC.
Condensed Consolidated Statements of Cash Flows
(Unaudited)
(In thousands)

	Three Months Ended March 31,	
	2022	**2021**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (18,591)	$ (8,066)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	151	180
Stock-based compensation	1,809	347
Change in fair value of warrant liability	—	(8)
Gain on asset disposal	(22)	—
Amortization of operating lease right-of-use assets	368	—
Net accretion and amortization in marketable securities	351	—
Amortization of debt issuance costs	29	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	607	70
Accounts payable	3,054	(294)
Accrued expenses and other liabilities	(1,552)	(227)
Operating lease liabilities	(368)	—
Net cash used in operating activities	(14,164)	(7,998)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(385)	(365)
Purchases of marketable securities	(65,506)	(24,082)
Proceeds from maturities of marketable securities	18,005	—
Net cash used in investing activities	(47,886)	(24,447)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payments on Series C issuance costs	(192)	(2,491)
Proceeds from stock option exercises	84	—
Payments on capital lease obligations	—	(32)
Net cash used in financing activities	(108)	(2,523)
Net decrease in cash, cash equivalents and restricted cash	(62,158)	(34,968)
Cash, cash equivalents and restricted cash at beginning of period	116,174	59,836
Cash, cash equivalents and restricted cash at end of period	$ 54,016	$ 24,868
SUPPLEMENTAL NON-CASH OPERATING INFORMATION:		
Right-of-use assets obtained in exchange for lease liabilities	$ 14,477	$ —
SUPPLEMENTAL NON-CASH INVESTING AND FINANCING INFORMATION:		
Property and equipment additions included in accounts payable and accrued liabilities	$ 1,396	$ —
Issuance costs for convertible preferred units included in accounts payable and accrued liabilities	$ —	$ 141
Accrued tax distributions	$ 14	$ 1
Reconciliation of cash, cash equivalents and restricted cash as shown in the condensed consolidated statement of cash flows		
Cash and cash equivalents	$ 53,668	$ 24,719
Restricted cash	348	149
Total cash, cash equivalents and restricted cash	$ 54,016	$ 24,868

See accompanying notes.

1. Organization and Description of Business

DICE Therapeutics, Inc. ("DICE", or the "Company"), a successor to DiCE Molecules Holdings, LLC ("DiCE LLC"), is a Delaware Corporation headquartered in South San Francisco, California. DICE is a biopharmaceutical company leveraging its proprietary technology platform to build a pipeline of novel oral therapeutic candidates to treat chronic diseases in immunology and other therapeutic areas. The Company's platform, DELSCAPE, is designed to discover selective oral small molecules with the potential to modulate protein-protein interactions ("PPIs") as effectively as systemic biologics.

Reverse Stock Split

On September 2, 2021, the DiCE LLC Board approved a reverse split of the Company's units at a 1-for-4 ratio (the "Reverse Stock Split"). The Reverse Stock Split became effective on September 8, 2021. All issued and outstanding common units, convertible preferred units, profits interest units, common unit warrants, convertible preferred unit warrants, and per share amounts contained in the condensed consolidated financial statements have been retroactively adjusted to reflect this Reverse Stock Split for all periods presented.

Liquidity

The Company has incurred significant operating losses since inception and has relied primarily on public and private equity to fund its operations. As of March 31, 2022, the Company had an accumulated deficit of $122.3 million. The Company expects to continue to incur substantial losses, and its ability to achieve and sustain profitability will depend on the successful development, approval, and commercialization of product candidates and on the achievement of sufficient revenue to support its cost structure. The Company may never achieve profitability, and until then, the Company will need to continue to raise additional capital. As of March 31, 2022, the Company had cash, cash equivalents, and marketable securities of $303.2 million. Based on the current plan, the Company believes that its cash, cash equivalents, and marketable securities as of March 31, 2022 provide sufficient capital resources to continue its operations for at least twelve months from the issuance date of these unaudited condensed consolidated financial statements.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in conformity with generally accepted accounting principles in the United States ("GAAP") as defined by the Financial Accounting Standards Board ("FASB"). The condensed consolidated financial statements include the accounts of DICE Therapeutics, Inc. and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of the accompanying condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of revenue and expense during the reporting period. The Company evaluates its estimates, including those related to revenue recognition, the fair value of convertible preferred stock warrants, income taxes uncertainties, stock-based compensation, including the fair value of common stock, lease assets and liabilities, clinical trial accruals, and related assumptions on an ongoing basis using historical experience and other factors, and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results could materially differ from those estimates.

Unaudited Interim Condensed Consolidated Financial Statements

The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all necessary adjustments, which include only normal recurring adjustments necessary to present fairly the Company's financial position as of March 31, 2022, and its results of operations and comprehensive loss and changes in stockholders' equity and members' deficit for the three months ended March 31, 2022 and 2021 and its cash flows for the three months ended March 31, 2022 and 2021. The financial data and the other financial information contained in these notes to the condensed consolidated financial statements related to the three month period are also unaudited. The results of operations for the three months ended March 31, 2022 are not necessarily indicative of the results to be expected for the year ending December 31, 2022 or for any other future annual or interim period. These condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements included in the Annual Report on Form 10-K for the year ended December 31, 2021, as filed on March 28, 2022. The Company's significant accounting policies are detailed in its Annual Report on Form 10-K for the year ended December 31, 2021.

Revenue Recognition

The Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive to in exchange for those goods or services. To determine revenue recognition for customer contracts, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that it will collect the consideration it is entitled to in exchange for the goods and services it transfers to the customer. At contract inception, the Company assesses the goods or services promised within each contract that falls under the scope of ASC Topic 606, Revenue from Contracts with Customers, and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

The Company enters into collaboration agreements under which it may obtain upfront license fees, research and development funding, and development, regulatory and commercial milestone payments, and royalty payments. The Company's performance obligations under these arrangements may include licenses of intellectual property, and research and development services.

In the collaboration agreements, the Company has a performance obligation to perform research and development services to identify compounds as therapeutic candidates against identified targets. The revenue is recognized as the research and development services are being performed and the results of the research and development services are provided to the customer. The customers have options to elect commercial licenses of intellectual property. As the customer options are not considered to be a material right, customer options are accounted for as separate contracts if and when they are exercised by the customer.

The Company is eligible to receive milestone payments under the collaborative arrangements. The Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price. If it is probable that a significant revenue reversal would not occur, the associated milestone value would be included in the transaction price. Milestone payments that are not within the Company's or the licensee's control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received.

Under the collaborative arrangements, the Company may be eligible to receive sales-based royalties, including milestone payments based on the level of sales, and in which the license is deemed to be the predominant item to which the royalties relate. The Company would recognize revenue when the related sales occur to earn the royalty or sales-based milestone payments.

Upfront payments and fees are recorded as deferred revenue upon receipt or when due, and may require deferral of revenue recognition to a future period until the Company performs its obligations under these arrangements. Amounts payable to the Company are recorded as accounts receivable when the Company's right to consideration is unconditional.

Leases

The Company adopted Accounting Standards Codification ("ASC") Topic 842, "Leases" ("ASC 842") on January 1, 2022 using the modified retrospective method. Under this method, financial statements for periods after the adoption date are presented in accordance with ASC 842 and prior-period financial statements continue to be presented in accordance with ASC 840, the accounting standard originally in effect for such periods. Under ASC 842, the Company determines if an arrangement is a lease at inception. Operating leases are included in operating lease right-of-use ("ROU") assets and the current and noncurrent operating lease liabilities are included as operating lease liabilities in the Company's condensed consolidated balance sheets.

ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized based on the present value of lease payments over the lease term at the commencement date of the lease and any amounts probable of being owed under a residual value guarantee (if applicable). ROU assets also include any initial direct costs incurred and any lease payments made at or before the lease commencement date, less any lease incentive received. As the Company's leases do not provide an implicit interest rate, the Company uses its incremental borrowing rate based on the information available at the commencement date in determining the present value of lease payments. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense for lease payments is recognized on a straight-line basis over the expected lease term.

The Company excludes from its condensed consolidated balance sheet recognition of leases having a term of 12 months or less (short-term leases) and does not separate lease components and non-lease components for its real estate leases. The Company's non-lease components are primarily related to property maintenance, which varies based on future outcomes, and is recognized in rent expense when incurred.

Recently Adopted Accounting Pronouncements

In 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Updates 2016-02, Leases ("ASU 2016-02"), with amendments issued in 2018 and 2019, which amended existing guidance to require substantially all leases to be recognized by lessees on their balance sheet as a right-of-use ("ROU") asset and corresponding lease liability, including leases previously accounted for as operating leases.

The Company adopted ASC 842 effective January 1, 2022. The Company elected the optional package of practical expedients to not reassess: (i) whether any expired or existing contracts are or contain leases; (ii) lease classification for any expired or existing leases; and (iii) whether initial direct costs qualify for capitalization on any existing leases. Upon adoption of ASC 842, on January 1, 2022, the Company recorded operating lease ROU assets of $0.5 million, operating lease liabilities of $0.5 million and derecognized the deferred rent liability of $8,000.

Recently Issued Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments-Credit Losses: Measurement of Credit Losses on Financial Instruments ("Topic 326"). This standard requires measurement and recognition of expected credit losses for financial assets. The FASB subsequently issued clarifications to this standard. This standard will become effective for the Company for fiscal years beginning after December 15, 2022. The Company does not expect the adoption of this standard to have a material impact on its condensed consolidated financial statements and related disclosures.

3. Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability, or an exit price, in the principal or most advantageous market for that asset or liability in an orderly transaction between market participants on the measurement date.

Fair value is measured based on a three-level hierarchy of inputs, of which the first two are considered observable and the last unobservable. Unobservable inputs reflect the Company's own assumptions about current market conditions. The use of observable inputs is maximized, where available, and the use of unobservable inputs is minimized when measuring fair value. The three-level hierarchy of inputs is as follows:

Level 1—Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;

Level 2—Inputs are observable, unadjusted quoted prices in active markets for similar assets or liabilities, unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and

Level 3—Unobservable inputs that are significant to the measurement of the fair value of the assets or liabilities that are supported by little or no market data.

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

The carrying amounts reflected in the condensed consolidated balance sheets for cash, restricted cash, accounts receivable, accounts payable and accrued liabilities approximate their fair values due to their short-term nature.

The following tables present the Company's assets and liabilities that are measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

	March 31, 2022			
	Level 1	Level 2	Level 3	Total
Money market funds	$ 53,239	$ —	$ —	$ 53,239
US treasuries	67,721	—	—	67,721
Government treasury and agency securities	—	6,020	—	6,020
Corporate securities and commercial paper	—	175,822	—	175,822
Total assets measured at fair value	$ 120,960	$ 181,842	$ —	$ 302,802

	December 31, 2021			
	Level 1	Level 2	Level 3	Total
Money market funds	$ 115,410	$ —	$ —	$ 115,410
US treasuries	24,053	—	—	24,053
Government treasury and agency securities	—	7,600	—	7,600
Corporate securities and commercial paper	—	171,842	—	171,842
Total assets measured at fair value	$ 139,463	$ 179,442	$ —	$ 318,905

The following table presents the changes in fair values of the Company's convertible preferred stock warrants and common stock warrants, classified as level 3 financial liabilities (in thousands):

	Three Months Ended March 31,	
	2022	2021
Beginning balance	$ —	$ 314
Change in fair value	—	(8)
Reclassification of fair value of warrants to equity upon the net exercise of warrants	—	—
Ending balance	$ —	$ 306

Prior to settlement, the fair value of the warrant liability was estimated using a hybrid approach between a probability-weighted expected return method (PWERM) and an option pricing model (OPM), which estimated the probability weighted value across multiple liquidity scenarios, while using OPM to estimate the allocation of value within one or more of those scenarios. The Company considered various scenarios, including a scenario in which the Company completes an IPO, a scenario in which the Company stays private, and a scenario contemplating a merger or acquisition.

4. Investments

The amortized cost, unrealized gain and loss, and fair value of the Company's investments in marketable securities by major security type are as follows (in thousands):

	March 31, 2022			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Fair Value
Money market funds	$ 53,239	$ —	$ —	$ 53,239
US treasuries	67,934	4	(217)	67,721
Government treasury and agency securities	6,044	—	(24)	6,020
Corporate securities and commercial paper	176,725	—	(903)	175,822
Total financial assets	$ 303,942	$ 4	$ (1,144)	$ 302,802

	December 31, 2021			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Fair Value
Money market funds	$ 115,410	$ —	$ —	$ 115,410
US treasuries	24,056	1	(4)	24,053
Government treasury and agency securities	7,606	—	(6)	7,600
Corporate securities and commercial paper	171,891	3	(52)	171,842
Total financial assets	$ 318,963	$ 4	$ (62)	$ 318,905

As of March 31, 2022, the fair value of the Company's marketable debt securities, by maturity date, were as follows (in thousands):

	Amount
Due within one year	$ 204,757
Due in one to five years	44,806
Total marketable securities	$ 249,563

5. Collaboration Revenue

2015 Sanofi Collaboration Agreement

In December 2015, the Company entered into a license and collaboration agreement (the "Sanofi Agreement") with Aventis, Inc. ("Sanofi"), which was amended and restated in August 2017 (as amended, the "2015 Collaboration Agreement"). Under the Sanofi Agreement, the Company agreed to provide research services on identified targets and to grant Sanofi an exclusive option to license to develop and commercialize (as applicable), certain compounds into products within the time frames specified therein. In particular, the Company agreed to identify, in two or more screening libraries, compounds that bind to seven agreed upon immuno-oncology targets and to generate collaboration compounds for use by Sanofi to develop and commercialize collaboration products.

Under the terms of the Sanofi Agreement, Sanofi has the exclusive rights and is responsible for the development, commercialization and manufacture of collaboration products resulting from the collaboration. Sanofi is obligated to use commercially reasonable efforts to commercialize at least one collaboration product for each target, within certain countries, upon regulatory approval of such product.

Upon signing the Sanofi Agreement in December 2015, Sanofi paid the Company an initial fee of $8.0 million for target exclusivity rights and an additional $1.0 million annual technology access and development fee. In December 2016, Sanofi paid the Company an additional $9.0 million fee for the same services.

At the date of the 2017 amendment to the Sanofi Agreement, the Company had remaining unrecognized revenue of $3.0 million from the Agreement to be recognized over the remaining term (August 2017 through December 2020) when research services were being provided. For the three months ended March 31, 2022 and 2021, no revenue was recognized related to the Sanofi Agreement, as amended, since the research services were completed in December 2020.

The performance obligation under the Sanofi Agreement, as amended, consisted of research services to create libraries with active compounds for assigned collaboration targets that can be developed into a drug for commercial use. In addition to the ongoing research services, the arrangement included several customer options.

Under the Sanofi Agreement, the Company earned Sum of the Evidence ("SOE") points depending on the milestone achieved and Sanofi's elections. In connection with this right, the Company recognized $2.0 million in revenue in 2018, when SOE points were earned. The $2.0 million contract asset is recorded as an unbilled receivable in the condensed consolidated balance sheets as of March 31, 2022 and December 31, 2021. The services provided by the Company under the Sanofi Agreement were completed in December 2020. There was no remaining deferred revenue as of March 31, 2022 and December 31, 2021.

In March 2022, Sanofi notified the Company that it no longer intended to develop therapeutic candidates under the Sanofi Agreement and terminated the agreement effective as of July 2022, or such earlier date as agreed by the respective parties. As a result, the Company will regain worldwide rights to the previously partnered oral immuno-oncology program.

2017 Genentech Collaboration Agreement

In November 2017, the Company entered into a collaboration agreement (the "Genentech Agreement") with Genentech, Inc. ("Genentech"). Under the 2017 Collaboration Agreement, the Company was entitled to receive a one-time target access fee for each of the collaboration targets designated. The research collaboration with respect to each collaboration target has a two-year term that commences upon the Company's initiation of certain research activities, unless terminated earlier under the terms of the Collaboration Agreement. On a per collaboration target basis, the Company is also eligible to receive preclinical, clinical, regulatory, and commercial milestone payments, as well as tiered low-single-digit royalties.

Upon execution of the Genentech Agreement, Genentech designated certain collaboration targets and paid the Company a $4.5 million target access fee. In 2018, Genentech paid the Company an additional $1.5 million in target access fees. The Company's performance obligation under the collaboration consists of research services. The revenue related to the performance obligation is recognized when the research services are completed and delivered to Genentech. In addition, the arrangement includes several customer options which will be accounted for as separate contracts if and when elected by Genentech.

The Company initiated research activities on the active collaboration targets in March 2018 and submitted five milestone packages for Genentech to review in 2019. The Company recognized collaboration revenue upon the completion of the milestone packages and research services. In June 2021, the Genentech Agreement was terminated, and the Company recognized the remaining $1.1 million of deferred revenue as collaboration revenue for the year ended December 31, 2021. No revenue was recognized for the three-month periods ended March 31, 2022 and 2021.

6. Leases

In June 2021, the Company entered into a lease agreement for a new office space in South San Francisco, California. The lease has an initial term of seven years, beginning on the lease commencement date of March 25, 2022, with an option to extend the lease for an additional period of five years. Under the terms of the lease, the Company is required to maintain a letter of credit for the benefit of the landlord in the amount of $0.2 million, commencing on the effective date of the agreement until the expiration of the lease. The deposit related to the letter of credit is included within restricted cash in the condensed consolidated balance sheets.

The Company leased its former headquarters with its main offices and laboratory facilities in South San Francisco under a sublease agreement that ended in April 2022.

As of March 31, 2022, the Company had recorded an aggregate operating lease ROU asset of $14.3 million and an aggregate operating lease liability of $14.1 million in the accompanying unaudited condensed consolidated balance sheet. As of March 31,2022, the weighted-average remaining lease term was 7.0 years and the weighted-average incremental borrowing rate used to determine the operating lease liability was 10.0%.

As of March 31, 2022, the future minimum payments under operating lease liabilities were as follows (in thousands):

	Amount
2022 (remaining nine months)	$ 1,862
2023	2,665
2024	2,738
2025	2,814
2026	2,891
Thereafter	6,792
Total undiscounted lease payments	19,762
Less: imputed interest	(5,653)
Total lease liabilities	14,109
Less: lease liabilities – current portion	1,173
Lease liabilities – noncurrent portion	$ 12,936

Operating lease cost for the three months ended March 31, 2022 was $0.4 million.

7. Stock-Based Compensation

2021 Equity Incentive Plan

In January 2022, the common stock available for issuance under the 2021 Equity Incentive Plan automatically increased by 5% of the total number of shares of the Company's capital stock outstanding on December 31, 2021, or 1,911,215 shares.

2021 Employee Stock Purchase Plan

In January 2022, the common stock available for issuance under the 2021 Employee Stock Purchase Plan automatically increased by 1% of the total number of shares of the Company's capital stock outstanding on December 31, 2021, or 382,243 shares.

Stock-Based Compensation Expense

The Company recognized stock-based compensation as follows (in thousands):

	Three Months Ended March 31,	
	2022	2021
Research and development	$ 974	$ 163
General and administrative	835	184
Total stock-based compensation expense	$ 1,809	$ 347

8. Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding during the period, less restricted stock subject to future vesting. Diluted net loss per share is the same as basic net loss per share for each period presented, as the effects of potentially dilutive securities are antidilutive given the net loss of the Company. The following outstanding shares have been excluded from the computation of diluted net loss per share for the three months ended March 31, 2022 and 2021 because their effect would have been anti-dilutive:

	March 31,	
	2022	2021
Convertible preferred units	—	12,690,540
Profit interest units	—	2,818,814
Warrants to purchase common units and convertible preferred units	—	64,003
Restricted stock subject to future vesting	923,116	—
Options to purchase common stock	1,931,836	—
Total	2,854,952	15,573,357

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

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our unaudited condensed consolidated financial statements and the related notes and other financial information included elsewhere in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K ("Annual Report") for the year ended December 31, 2021.

As discussed in the section titled "Special Note Regarding Forward Looking Statements," the following discussion and analysis contains forward-looking statements that involve risks and uncertainties. Our actual results and the timing of selected events could differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those set forth in the section titled "Risk Factors" under Part II, Item 1A below. Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to the "Company," "DICE," "we," "us" and "our" refer to DICE Therapeutics, Inc. and its wholly-owned subsidiaries.

Overview

We are a biopharmaceutical company leveraging our proprietary technology platform to build a pipeline of novel oral therapeutic candidates to treat chronic diseases in immunology and other therapeutic areas. We are initially focused on developing oral therapeutics against well-validated targets in immunology, with the goal of achieving comparable potency to their systemic biologic counterparts, which have demonstrated the greatest therapeutic benefit to date in these disease areas. Our platform, which we refer to as DELSCAPE, is designed to discover selective oral small molecules with the potential to modulate protein-protein interactions ("PPIs") as effectively as systemic biologics. We believe there is a significant unmet medical need for convenient oral therapies in chronic immunological diseases that offer the therapeutic benefits of systemic biologics.

Our lead therapeutic candidate, DC-806, is an oral antagonist of the pro-inflammatory signaling molecule, interleukin-17 ("IL-17"), which is a validated drug target implicated in a variety of immunology indications. There are two approved antibody therapeutics, COSENTYX (secukinumab), marketed by Novartis, and TALTZ (ixekizumab), marketed by Eli Lilly, but no oral therapies targeting this pathway. COSENTYX and TALTZ both are approved for the treatment of psoriasis, psoriatic arthritis, ankylosing spondylitis and nonradiographic axial spondyloarthritis, and collectively generated approximately $6.9 billion in worldwide sales in 2021. The Medicines and Healthcare Products Regulatory Agency ("MHRA") in the United Kingdom ("UK") approved our Clinical Trial Application ("CTA") for DC-806 in September 2021 and we are currently conducting a Phase 1 clinical trial in healthy volunteers and psoriasis patients. The Phase 1 trial is designed to generate safety and pharmacokinetic data, as well as provide early clinical proof-of-concept in psoriasis patients. The trial is being conducted in three overlapping cohorts: Phase 1a (single ascending dose) and Phase 1b (multiple ascending dose) in healthy volunteers, and a proof-of-concept Phase 1c in psoriasis patients. Topline data for the Phase 1 study are expected in mid-2022.

We also are developing oral therapeutic candidates targeting α4ß7 integrin and αVß1/αVß6 integrin for the treatment of inflammatory bowel disease ("IBD") and idiopathic pulmonary fibrosis ("IPF"), respectively. We plan to nominate therapeutic candidates for these programs by the end of 2022, in the case of α4ß7, and by the end of 2023, in the case of αVß1/αVß6. Additionally, we will regain worldwide rights by July 2022 to a previously partnered oral immuno-oncology program, small-molecule PD-L1 inhibitors discovered using our DELSCAPE platform. Leveraging DELSCAPE, we are also evaluating other novel and validated immunology targets, including interleukin-23 ("IL-23"), tumor necrosis factor α ("TNFα"), neonatal Fc receptor ("FcRn"), and thymic stromal lymphopoietin ("TSLP"), among other potential targets, with a view toward advancing one or more programs into clinical development.

Currently, all of our preclinical and clinical drug manufacturing, storage, distribution or quality testing is outsourced to third-party manufacturers. As our development programs progress and we build new process efficiencies, we expect to continually evaluate this strategy with the objective of satisfying demand for registration trials and, if approved, the manufacture, sale and distribution of commercial products.

On September 17, 2021, we closed our initial public offering ("IPO") in which we sold an aggregate of 13,800,000 shares of common stock at a price to the public of $17.00 per share, which included 1,800,000 shares issued upon the full exercise by the underwriters of their option to purchase additional shares of common stock. We

received aggregate net proceeds from the IPO of approximately $214.7 million, after deducting underwriting discounts and offering costs.

Our revenue to date has been generated solely from research collaborations and activities. We have not had any products approved for sale and have not generated any revenue from product sales. Further, we do not expect to generate revenue from product sales until such time, if ever, that we are able to successfully complete the development and obtain marketing approval for one of our therapeutic candidates. We have incurred net losses in each year since inception except for the year ended December 31, 2016 and expect to continue to incur net losses for the foreseeable future. Our ability to generate product revenue will depend on the successful development and eventual commercialization of one or more of our therapeutic candidates. Our net losses were $18.6 million and $8.1 million for the three months ended March 31, 2022 and 2021, respectively. As of March 31, 2022, we had an accumulated deficit of $122.3 million. Our net losses may fluctuate significantly from period to period, depending on the timing and expenditures of our research and development activities.

Business Impact of the COVID-19 Pandemic

We are subject to risks and uncertainties as a result of the ongoing COVID-19 pandemic. We have experienced, and may further experience, disruptions, pauses and/or delays that have and could further adversely impact our business operations, and/or associated timelines. As we gradually return to work in accordance with state and local regulations, we maintain flexible work-from-home procedures for all employees other than for those personnel and contractors who perform essential activities that must be completed on-site. If negative developments relating to the pandemic worsen, we may be required to restrict on-site staff at our offices and laboratories again. With respect to the development of our IL-17 franchise, other research programs in our pipeline and certain aspects of our supply chain, we may experience disruption if our third-party suppliers and manufacturers pause their operations again in response to such negative developments and/or as a result of national and local regulations. In addition, we may experience potential disruption to enrollment and conduct of our current or anticipated future clinical trials due to the COVID-19 pandemic. We will continue to monitor the situation closely and may take further actions that alter our operations, including those that may be required by federal, state or local authorities, or that we determine are in the best interests of our employees and other third parties with whom we do business. At this point, the full extent to which the COVID-19 pandemic may affect our business, operations and development timelines and plans, in particular with our lead therapeutic candidate in clinical trials, remains uncertain and is subject to change.

Collaboration Agreements

Sanofi

In December 2015, we entered into a license and collaboration agreement with Sanofi, which was amended and restated in August 2017 (as amended, the “Sanofi Agreement”), under which we agreed to grant Sanofi an exclusive option to license to develop and commercialize (as applicable), certain compounds into products.

Upon the signing of the Sanofi Agreement in December 2015, Sanofi paid us an initial fee of $8.0 million for target exclusivity rights and an additional $1.0 million annual technology access and development fees. In December 2016, Sanofi paid us an additional $9.0 million fee for the same services. In connection with the right to earn Sum of Evidence (“SOE”) points under the Sanofi Agreement, we recognized $2.0 million in revenue in 2018, when SOE points were earned. The $2.0 million contract asset is recorded as an unbilled receivable as of March 31, 2022 and December 31, 2021.

In March 2022, Sanofi notified us that it no longer intended to develop therapeutic candidates under the Sanofi Agreement and terminated the agreement, effective July 2022 unless otherwise agreed by the parties. As a result, we will regain worldwide rights to the program. We do not expect to recognize any further revenue from this arrangement.

Genentech

In November 2017, we entered into a collaboration agreement ("Genentech Agreement") with Genentech, Inc. In June 2021, the collaboration research program was terminated.

Components of Results of Operations

Operating Expenses

Research and Development

Research and development expenses account for a significant portion of our operating expenses. A significant portion of our research and development costs have been external costs, which we track by stage of development, preclinical or clinical. However, we do not track our indirect costs on a program specific basis because these costs are deployed across multiple projects and, as such, are not separately classified. Since our IL-17 program has completed IND-enabling studies and has entered into Phase 1 clinical trials, we have separately presented the external costs associated with that program.

We anticipate that our research and development expenses will increase substantially in absolute dollars in future periods as we continue to invest in research and development activities related to developing our therapeutic candidates, as our therapeutic candidates advance into later stages of development, as we begin to conduct larger clinical trials, as we seek regulatory approvals for any therapeutic candidates that successfully complete clinical trials, and as we incur expenses associated with hiring additional personnel to support our research and development efforts.

General and Administrative

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research activities and development of our programs. We also anticipate that we will incur increased expenses as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the SEC and those of any national securities exchange on which our securities are traded, legal, auditing, additional insurance expenses, investor relations activities, and other administrative and professional services. As a result, we expect that our general and administrative expenses will increase substantially in absolute dollars in future periods.

Results of Operations

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

The following table summarizes our results of operations for the three months ended March 31, 2022 and 2021 (in thousands, except percentages):

	Three Months Ended March 31,		$	%
	2022	2021	Change	Change
Operating expenses:				
Research and development	$ 13,410	$ 6,621	$ 6,789	103%
General and administrative	5,448	1,465	3,983	272%
Total operating expenses	18,858	8,086	10,772	133%
Loss from operations	(18,858)	(8,086)	(10,772)	133%
Other income (expense):				
Interest and other income, net	327	14	313	*
Interest expense	(60)	(2)	(58)	*
Change in fair value of warrant liability	—	8	(8)	-100%
Net loss	$ (18,591)	$ (8,066)	$ (10,525)	130%

* *Not meaningful*

Operating Expenses

Research and Development Expenses

Research and development expenses were $13.4 million for the three months ended March 31, 2022, compared to $6.6 million for the three months ended March 31, 2021. The increase of $6.8 million was primarily due to an increase of $4.2 million related to the advancement of our IL-17 franchise. Additionally, personnel-related expenses increased by $1.9 million due to an increase in headcount and stock-based compensation. The following table summarizes our research and development expenses for the three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,		$
	2022	2021	Change
Direct costs:			
IL-17	$ 7,822	$ 3,586	$ 4,236
Other programs	1,397	864	533
Indirect costs:			
Personnel-related expenses (including stock-based compensation)	3,584	1,672	1,912
Facilities and other expenses	607	499	108
Total research and development expenses	$ 13,410	$ 6,621	$ 6,789

General and Administrative Expenses

General and administrative expenses were $5.5 million for the three months ended March 31, 2022, compared to $1.5 million for the three months ended March 31, 2021. The increase of $4.0 million was primarily due to a $1.5 million increase in personnel related costs related to an increase in headcount and stock-based compensation. Additionally, professional service fees increased by $0.8 million and general corporate expenses increased by $0.9 million.

Liquidity and Capital Resources

Since our inception through March 31, 2022, our operations have been financed primarily by sales of our convertible preferred stock and common stock, through our collaboration agreements, and issuance of debt. In September 2021, we completed our IPO for aggregate proceeds of approximately $214.7 million (inclusive of the full exercise of the underwriters' option to purchase additional shares), net of offering costs, underwriter discounts and commissions. As of March 31, 2022, we had $303.2 million of cash, cash equivalents and marketable securities, and an accumulated deficit of $122.3 million.

Based on our current business plans, we believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our planned operations through mid-2024. Our cash, cash equivalents and marketable securities include money market funds, government agency securities, corporate debt and commercial paper. We maintain established guidelines relating to diversification and maturities of our investments to preserve principal and maintain liquidity.

Our material cash requirements include our senior secured term loan facility with Silicon Valley Bank under which we borrowed $2.5 million and have an option to borrow up to $5.0 million in additional term loans through June 30, 2022, subject to our achieving certain development milestones related to our IL-17 program. Within the next twelve months we are scheduled to make principal payments of $0.7 million under the senior term loan facility. We also have contractual obligations for our operating leases for our corporate headquarters. Our undiscounted future lease payments are $19.8 million, of which we are obligated to make lease payments of $2.4 million in the next twelve months.

Funding Requirements

Our primary use of cash is to fund operating expenses, most significantly research and development 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, accrued expenses and prepaid expenses.

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

We will need additional funds to meet operational needs and capital requirements for clinical trials, other research and development expenditures, and business development activities. 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 clinical studies.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, existing stockholders' ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect existing stockholders' rights as common stockholders. 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 acquisitions or capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or drug candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Cash Flows

The following table summarizes our cash flows for the periods indicated (in thousands):

	Three Months Ended March 31,	
	2022	2021
Net cash used in:		
Operating activities	$ (14,164)	$ (7,998)
Investing activities	(47,886)	(24,447)
Financing activities	(108)	(2,523)
Net decrease in cash, cash equivalents, and restricted cash	$ (62,158)	$ (34,968)

Net Cash Used in Operating Activities

For the three months ended March 31, 2022, net cash used in operating activities was $14.2 million. The net cash outflow from operations primarily resulted from our net loss of $18.6 million, partially offset by changes in net operating assets and liabilities of $1.7 million, and non-cash charges of $2.7 million consisting primarily of: $1.8 million in stock-based compensation; $0.4 million of net accretion and amortization of marketable securities; $0.3 million of amortization of operating lease right-of-use assets; and $0.2 million for depreciation. The change in net operating assets and liabilities was primarily due to a $3.0 million increase in accounts payable, primarily due to timing of payments, and a $0.6 million decrease in prepaid expenses and other assets, partially offset by a $1.5 million decrease in accrued expenses and other liabilities and by a $0.4 million decrease in operating lease liabilities.

For the three months ended March 31, 2021, net cash used in operating activities was $8.0 million. The net cash outflow from operations primarily resulted from our net loss of $8.1 million and change in net operating assets and liabilities of $0.5 million, partially offset by non-cash charges of $0.5 million consisting primarily of $0.2 million for depreciation and amortization and $0.3 million in stock-based compensation. The change in net operating assets and liabilities was primarily due to a $0.5 million decrease in accounts payable and accrued liabilities, primarily due to timing of payments, partially offset by a $0.1 million decrease in prepaid expenses and other current assets.

Net Cash Used in Investing Activities

For the three months ended March 31, 2022, net cash used in investing activities was $47.9 million due to the net purchase of marketable securities of $47.5 million and purchase of property and equipment of $0.4 million.

For the three months ended March 31, 2021, net cash used in investing activities was $24.4 million due to the purchase of marketable securities of $24.1 million and purchases of property and equipment of $0.3 million.

Net Cash Used in Financing Activities

For the three months ended March 31, 2022, net cash used in financing activities was $0.1 million due to the payment of issuance costs for Series C preferred units of $0.2 million, partially offset by cash proceeds from the exercise of stock options of $0.1 million.

For the three months ended March 31, 2021, net cash used in financing activities was $2.5 million due to the payment of issuance costs for Series C preferred units.

Critical Accounting Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

During the three months ended March 31, 2022, there were no material changes to our critical accounting estimates or in the methodology used for estimates from those described in "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report.

Recent Accounting Pronouncements

See Note 2 to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for more information.

Emerging Growth Company and Smaller Reporting Company Status

We are an "emerging growth company," as defined in the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies.

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

We are also a ''smaller reporting company,'' meaning that the market value of our stock held by non-affiliates is less than $700 million and our annual revenue was less than $100 million during our most recently completed fiscal year. We may continue to be a smaller reporting company for so long as (i) the market value of our stock held by non-affiliates is less than $250 million or (ii) our annual revenue is less than $100 million during our most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million.

If we are a smaller reporting company at the time we cease to be an emerging growth company ("EGC"), we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to EGCs, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation and supervision of our Chief Executive Officer and our Chief Financial Officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures are effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) during the quarter ended March 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II-OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may be involved in legal proceedings arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, in the opinion of management, would have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity and reputational harm, and other factors.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. Before making your decision to invest in shares of our common stock, you should carefully consider the risks described below, together with the other information contained in this Quarterly Report on Form 10-Q, including in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and in our unaudited condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q. We cannot assure you that any of the events discussed below will not occur. These events could have a material and adverse impact on our business, financial condition, results of operations and prospects. If that were to happen, the trading price of our common stock could decline, and you could lose all or part of your investment.

Risk Factors Summary

Our business is subject to a number of risks and uncertainties, including those risks discussed at-length below. These risks include, among others, the following:

- We are a clinical stage biopharmaceutical company with a limited operating history and no products approved for commercial sale.
- We have never generated revenue from product sales and may never be profitable.
- We have incurred significant losses since our inception and we anticipate that we will continue to incur losses for the foreseeable future, which could harm our future business prospects.
- We will require substantial additional funds to advance development of our current or future therapeutic candidates, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development programs, commercialization efforts or other operations.
- Our therapeutic candidates are in early stages of development and may fail in development or suffer delays that materially and adversely affect their commercial viability. If we or our collaborators are unable to complete development of, or commercialize our therapeutic candidates, or experience significant delays in doing so, our business will be materially harmed.
- Our business is heavily dependent on the success of our lead therapeutic candidate, DC-806, fast follower therapeutic candidate DC-853, and related compounds in our IL-17 program. Existing and future preclinical studies and clinical trials of our therapeutic candidates may not be successful, and if we are unable to commercialize our therapeutic candidates or experience significant delays in doing so, our business will be materially harmed.
- If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of our therapeutics may be delayed and, as a result, our stock price may decline.
- Our approach to the discovery and development of our therapeutic treatments is based on novel technologies that are unproven and may not result in marketable products.
- Preclinical and clinical development involve a lengthy and expensive process, with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our current therapeutic candidates or any future therapeutic candidates.

- The COVID-19 pandemic could adversely impact our business, including our ongoing and anticipated future clinical trials, supply chain and business development activities.
- Results of preclinical studies and early clinical trials on any of our therapeutic candidates may not be predictive of results of future clinical trials.
- Preliminary, interim or topline data from our 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.
- Our future clinical trials or those of our future collaborators may reveal significant adverse events not seen in our preclinical studies or clinical trials and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our therapeutic candidates.
- We may not be successful in our efforts to use our DELSCAPE platform to expand our pipeline of therapeutic candidates and develop marketable products.
- We face competition from entities that have developed or may develop therapeutic candidates for the diseases addressed by our therapeutic candidates, including companies developing novel treatments and technology platforms. If these companies develop technologies or therapeutic candidates more rapidly than we do or their technologies are more effective, our ability to develop and successfully commercialize therapeutic candidates may be adversely affected.
- We have historically entered into collaborations and may, in the future, seek to enter into collaborations with third parties for the discovery, development and commercialization of our therapeutic candidates. If our future collaborators cease development efforts under collaboration agreements, or if those agreements are terminated, the collaborations may fail to lead to commercial products, and we may never receive milestone payments or future royalties under the agreements.
- The manufacturing of our small molecules is complex, and our third-party manufacturers may encounter difficulties in production. If we or any of our third-party manufacturers encounter such difficulties, our ability to provide supply of our therapeutic candidates for clinical trials, our ability to obtain marketing approval, or our ability to provide supply of our therapeutics for patients, if approved, could be delayed or stopped.
- We will need to grow our organization, and we may experience difficulties in managing our growth and expanding our operations, which could adversely affect our business.
- If we are unable to obtain and maintain sufficient intellectual property protection for our therapeutic candidates, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our therapeutics may be adversely affected.
- We and/or our collaborators may be unable to obtain, or may be delayed in obtaining, U.S. or foreign regulatory approval and, as a result, unable to commercialize our therapeutic candidates.

Risks Related to Our Financial Position and Need for Capital

We are a clinical stage biopharmaceutical company with a limited operating history and no therapeutics approved for commercial sale.

We are a clinical stage biopharmaceutical company with a limited operating history on which to base your investment decision. We have no therapeutics approved for commercial sale and have not generated any revenue from commercial therapeutic sales. Biopharmaceutical therapeutic development is a highly speculative undertaking because it entails substantial upfront capital expenditures and significant risk that any potential therapeutic candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval or become commercially viable.

We have identified DC-806 as our lead therapeutic candidate for our IL-17 program, which is now in the clinical development stage. We will continue to incur significant research and development and other expenses related to our

clinical development and ongoing operations. For the years ended December 31, 2021 and December 31, 2020, our net losses were approximately $49.0 million and $23.7 million, respectively, and for the three months ended March 31, 2022 and 2021, our net losses were $18.6 million and $8.1 million, respectively. As of March 31, 2022, we had an accumulated deficit of approximately $122.3 million. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of our therapeutic candidates.

We anticipate that our expenses will increase substantially if, and as, we:

- conduct clinical trials for our lead therapeutic candidate, DC-806, fast follower therapeutic candidate, DC-853, and related compounds in the IL-17 program, and any future therapeutic candidates within the IL-17 program and other programs;
- discover and develop new therapeutic candidates, and conduct research and development activities, preclinical studies and clinical trials;
- manufacture, or have manufactured, preclinical, clinical and commercial supplies of our therapeutic candidates;
- seek regulatory approvals for our therapeutic candidates or any future therapeutic candidates;
- commercialize our current therapeutic candidates or any future therapeutic candidates, if approved;
- attempt to transition from a company with a research focus to a company capable of supporting commercial activities, including establishing sales, marketing and distribution infrastructure;
- attract, hire and retain qualified clinical, scientific and management personnel;
- add operational, financial and management information systems and personnel;
- identify additional compounds or therapeutic candidates and acquire rights from third parties to those compounds or therapeutic candidates through licenses; protect our rights in our intellectual property portfolio;
- are impacted by increasing wage inflation;
- defend against third-party interference or infringement claims, if any;
- address any competing therapies and technological and market developments;
- experience any delays in our preclinical or clinical studies and regulatory approval for our therapeutic candidates due to the impacts of the COVID-19 pandemic; and
- incur additional costs associated with operating as a public company.

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

We have never generated revenue from therapeutic sales and may never be profitable.

Our ability to become and remain profitable depends on our ability to generate revenue. We do not expect to generate significant revenue, if any, unless and until we, either alone or with a collaborator, are able to obtain regulatory approval for, and successfully commercialize, our lead therapeutic candidate, fast follower therapeutic candidate or any other therapeutic candidates we may develop. Successful commercialization will require achievement of many key milestones, including demonstrating safety and efficacy in clinical trials, obtaining regulatory, including marketing, approval for these therapeutic candidates, manufacturing, marketing and selling

those therapeutics for which we, or any of our current or future collaborators, may obtain regulatory approval, satisfying any post-marketing requirements and obtaining reimbursement for our current or future therapeutics from private insurance or government payors. Because of the uncertainties and risks associated with these activities, we are unable to accurately and precisely predict the timing and amount of revenue, the extent of any further losses or if or when we might achieve profitability. We and any current or future collaborators may never succeed in these activities and, even if we do, or any collaborators do, we may never generate revenue that are large enough for us to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Additionally, our expenses could increase if we are required by the U.S. Food and Drug Administration ("FDA"), the UK's Medicines and Healthcare products Regulatory Agency ("MHRA"), or any comparable foreign regulatory authority to perform clinical trials in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any of our current or future therapeutic candidates.

Our failure to become and remain profitable may depress the market price of our common stock and could impair our ability to raise capital, expand our business or continue our operations. If we continue to suffer losses as we have in the past, investors may not receive any return on their investment and may lose their entire investment.

We will require substantial additional funds to advance development of our current or future therapeutic candidates, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our therapeutic development programs, commercialization efforts or other operations.

The development of biopharmaceutical therapeutic candidates, including conducting preclinical studies and clinical trials, is a very time-consuming, capital-intensive and uncertain process that takes years to complete. As our therapeutic candidates enter and advance through preclinical studies and clinical trials, we will need substantial additional funds to expand or create our development, regulatory, manufacturing, marketing and sales capabilities. We have used substantial funds to develop our technology and our therapeutic candidates and will require significant funds to conduct further research and development and preclinical testing and clinical trials of our therapeutic candidates, to seek regulatory approvals for our therapeutic candidates and to manufacture and market products, if any, which are approved for commercial sale. In addition, we expect to incur additional costs associated with operating as a public company.

Since our inception, we have invested a significant portion of our efforts and financial resources in research and development activities for our therapeutic candidates from the IL-17 program. Conducting preclinical studies and clinical trials for our therapeutic candidates will require substantial funds to complete. As of March 31, 2022, we had $303.2 million in cash, cash equivalents, and marketable securities. We expect to incur substantial expenditures in the foreseeable future as we seek to advance our lead therapeutic candidate and fast follower candidate from the IL-17 program, and any future therapeutic candidates through preclinical and clinical development, the regulatory approval process and, if approved, commercial launch activities. Based on our current operating plan, we believe that our existing cash, cash equivalents, and marketable securities will be sufficient to fund our anticipated operating expenses and capital expenditure requirements through at least the next 12 months from the filing of this Quarterly Report on Form 10-Q. However, our future capital requirements and the period for which we expect our existing resources to support our operations, fund expansion, develop new or enhanced therapeutics, or otherwise respond to competitive pressures, may vary significantly from what we expect and we may need to seek additional funds sooner than planned. Our monthly spending levels vary based on new and ongoing research and development and other corporate activities. Because the length of time and activities associated with successful research and development of our therapeutic candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any marketing and commercialization activities for approved therapeutics. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the timing, cost and progress of preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;
- the progress of the development efforts of parties with whom we have entered or may in the future enter into collaborations and/or research and development agreements;

- the timing and amount of milestone and other payments we may receive or make under our collaboration agreements;
- our ability to maintain our current licenses and research and development programs and to establish new collaboration arrangements;
- the costs involved in prosecuting and enforcing patent and other intellectual property claims;
- the costs of manufacturing our therapeutic candidates by third parties;
- the cost of regulatory submissions and timing of regulatory approvals;
- the cost of commercialization activities if our therapeutic candidates or any future therapeutic candidates are approved for sale, including marketing, sales and distribution costs;
- our efforts to enhance operational systems and hire additional personnel, including personnel to support development of our therapeutic candidates; and
- our need to implement additional internal systems and infrastructure, including financial and reporting systems to satisfy our obligations as a public company.

If we are unable to obtain funding on a timely basis or on acceptable terms, we may have to delay, reduce or terminate our research and development programs and preclinical studies or clinical trials, limit strategic opportunities or undergo reductions in our workforce or other corporate restructuring activities. We do not expect to realize revenue from sales of commercial therapeutics or royalties from licensed therapeutics in the foreseeable future, if at all, and, in no event, before our therapeutic candidates are clinically tested, approved for commercialization and successfully marketed. To date, we have primarily financed our operations through the issuance and sale of common stock, convertible preferred units and warrants, as well as payments received under our collaboration agreements.

We will be required to seek additional funding in the future and currently intend to do so through additional collaborations and/or licensing agreements, public or private equity offerings or debt financings, credit or loan facilities, or a combination of one or more of these funding sources. In addition, our Loan and Security Agreement with Silicon Valley Bank (the “SVB Loan and Security Agreement”) contains restrictive covenants that prevent us from, among other things, incurring additional indebtedness without SVB’s consent. Such restrictive covenants include affirmative covenants requiring, among other things, that we maintain our legal existence and good standing and obtain all government approvals, deliver certain financial reports and maintain certain intellectual property rights. Such restrictive covenants also include certain negative covenants include, among other things, certain restrictions on asset dispositions, changing our business, engaging in mergers and acquisitions, paying dividends or making certain other distributions, and creating other liens on our assets. If we default under the SVB Loan and Security Agreement, SVB will be able to declare all obligations immediately due and payable and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Further, if we are liquidated, SVB’s rights to repayment would be senior to the rights of the holders of our common units to receive any proceeds from the liquidation. SVB could declare a default under the Loan and Security Agreement upon the occurrence of any event that SVB interprets as a material adverse change as defined under the SVB Loan and Security Agreement, thereby requiring us to repay the loan immediately or to attempt to reverse the declaration of default through negotiation or litigation. Any declaration by SVB of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. For additional details, see the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources.”

If we raise additional funds by issuing equity securities, our stockholders will suffer dilution and the terms of any financing may adversely affect the rights of our stockholders. In addition, as a condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. Our future debt financings, if available, are likely to involve restrictive covenants limiting our flexibility in conducting future business activities, and, in the event of insolvency, debt holders would be repaid before holders of our equity securities received any distribution of our corporate assets. If we raise additional funds through licensing or collaboration arrangements with third parties, we may have to relinquish valuable rights to our therapeutic candidates, or grant licenses on terms that are not favorable to us. We also could be required to seek collaborators

for a therapeutic candidate at an earlier stage than otherwise would be desirable or relinquish our rights to therapeutic candidates or technologies that we otherwise would seek to develop or commercialize ourselves. Failure to obtain capital when needed on acceptable terms may force us to delay, limit or terminate our therapeutic development and commercialization of our current or future therapeutic candidates, which could have a material and adverse effect on our business, financial condition, results of operations and prospects.

We have incurred significant losses since our inception and we anticipate that we will continue to incur significant losses for the foreseeable future, which could harm our future business prospects.

We have historically incurred substantial net losses, including net losses of $49.0 million and $23.7 million for the years ended December 31, 2021 and 2020, respectively, and net losses of $18.6 million and $8.1 million for the three months ended March 31, 2022 and 2021, respectively. As of March 31, 2022, we had an accumulated deficit of $122.3 million. We expect our losses to continue as we continue to devote a substantial portion of our resources to our research and development efforts. These losses have had, and will continue to have, an adverse effect on our working capital, total assets, and members deficit/stockholders' equity. Because of the numerous risks and uncertainties associated with our research and development, we are unable to predict when we will become profitable, and we may never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our inability to achieve and then maintain profitability would negatively affect our business, financial condition, results of operations, and cash flows.

Risks Related to Discovery, Development and Commercialization

Our therapeutic candidates are in early stages of development and may fail in development or suffer delays that materially and adversely affect their commercial viability. If we or our collaborators are unable to complete development of, or commercialize our therapeutic candidates, or experience significant delays in doing so, our business will be materially harmed.

We have no therapeutics on the market and all of our therapeutic candidates are in early stages of development. Our Clinical Trial Application ("CTA"), with respect to DC-806, our lead therapeutic candidate from our IL-17 program, was approved by the MHRA in the UK in September 2021, and we began dosing for our clinical Phase 1 trial in October 2021. Additionally, we have a portfolio of targets and programs that are in earlier stages of discovery or preclinical development and may never advance to clinical-stage development. Our ability to achieve and sustain profitability depends on obtaining regulatory approvals for, and successfully commercializing our therapeutic candidates, either alone or with third parties, and we cannot guarantee you that we will ever obtain regulatory approval for any of our therapeutic candidates. We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals including approval by the MHRA and the FDA. Before obtaining regulatory approval for the commercial distribution of our therapeutic candidates, we or an existing or future collaborator must conduct extensive preclinical tests and clinical trials to demonstrate the safety and efficacy in humans of our therapeutic candidates.

We may not have the financial resources to continue development of, or to modify existing or enter into new collaborations for, a therapeutic candidate if we experience any issues that delay or prevent regulatory approval of, or our ability to commercialize, therapeutic candidates, including:

- preclinical study results may show the therapeutic candidate to be less effective than desired or to have harmful or problematic side effects;
- negative or inconclusive results from our clinical trials or the clinical trials of others for therapeutic candidates similar to ours, leading to a decision or requirement to conduct additional preclinical testing or clinical trials or abandon a program;
- product-related side effects experienced by patients in our clinical trials or by individuals using drugs or therapeutic biologics similar to our therapeutic candidates;
- our third-party manufacturers' inability to successfully manufacture our therapeutics;

- inability of any third-party contract manufacturer to scale up manufacturing of our therapeutic candidates and those of our collaborators to supply the needs of clinical trials or commercial sales;
- delays in submitting CTAs, Investigational New Drug applications ("INDs") or comparable foreign applications or delays or failures in obtaining the necessary approvals from regulators to commence a clinical trial, or a suspension or termination of a clinical trial once commenced;
- preclinical studies conducted outside of the United States may be affected by tariffs or import/export restrictions imposed by the United States or other governments;
- conditions imposed by the FDA, the MHRA or comparable foreign authorities regarding the scope or design of our clinical trials;
- delays in enrolling patients in our clinical trials;
- high drop-out rates of our clinical trial patients;
- inadequate supply or quality of therapeutic candidate components or materials or other supplies necessary for the conduct of our clinical trials;
- inability to obtain alternative sources of supply for which we have a single source for therapeutic candidate components or materials;
- greater than anticipated costs of our clinical trials;
- manufacturing costs, formulation issues, pricing or reimbursement issues, or other factors that no longer make a therapeutic candidate economically feasible;
- harmful side effects or inability of our therapeutic candidates to meet efficacy endpoints during clinical trials;
- failure to demonstrate a benefit-risk profile acceptable to the FDA, the MHRA or other regulatory agencies;
- unfavorable FDA, MHRA or other regulatory agency inspection and review of one or more clinical trial sites or manufacturing facilities used in the testing and manufacture of any of our therapeutic candidates;
- failure of our third-party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all;
- delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our technology in particular or as a result of the impacts of the COVID-19 pandemic; or
- varying interpretations of our data by the FDA, the MHRA and similar foreign regulatory agencies.

We or our collaborators' inability to complete development of, or commercialize our therapeutic candidates, or significant delays in doing so due to one or more of these factors, could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Our business is heavily dependent on the success of our lead therapeutic candidate, DC-806, fast follower therapeutic candidate DC-853, and related compounds in our IL-17 program. Existing and future preclinical studies and clinical trials of our therapeutic candidates may not be successful, and if we are unable to commercialize our therapeutic candidates or experience significant delays in doing so, our business will be materially harmed.

We have invested a significant portion of our efforts and financial resources in the development of our lead therapeutic candidate, DC-806, fast follower therapeutic candidate DC-853, and related compounds in our IL-17 program. Our ability to generate commercial product revenue, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our lead therapeutic candidate. In September 2021, the MHRA approved our CTA for DC-806, our lead therapeutic candidate from our IL-17 program. In October 2021, we commenced our Phase 1 clinical trial. We have not previously submitted a new drug application ("NDA") to the FDA, or any other similar regulatory approval filings to the MHRA or comparable foreign authorities, for therapeutic candidates, and we cannot be certain that our therapeutic candidates will be

successful in clinical trials or receive regulatory approval. Further, our therapeutic candidates may not receive regulatory approval even if they are successful in clinical trials. In addition, regulatory authorities may not complete their review processes in a timely manner, or additional delays may result if an FDA Advisory Committee, the MHRA or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical trials and the review process. Regulatory authorities also may approve a therapeutic candidate for more limited indications than requested or with labeling that includes warnings, contraindications or precautions with respect to conditions of use. Regulatory authorities may also require Risk Evaluation and Mitigation Strategies ("REMS") or the performance of costly post-marketing clinical trials. If we do not receive regulatory approvals for our therapeutic candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market our therapeutic candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets for patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenue from sales of such therapeutics, if approved.

We plan to seek regulatory approval to commercialize our therapeutic candidates in the UK, the United States, the European Union ("EU") and in other selected countries. In order to obtain separate regulatory approvals in other countries, we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy. Other countries also have their own regulations governing, among other things, clinical trials and commercial sales, as well as pricing and distribution of our therapeutic candidates, and we may be required to expend significant resources to obtain regulatory approval, which may not be successful, and to comply with ongoing regulations in these jurisdictions.

The success of our lead therapeutic candidate, DC-806, fast follower therapeutic candidate DC-853, and related compounds in the IL-17 program, and our other therapeutic candidates will depend on many factors, including the following:

- successful completion of necessary preclinical studies to enable the initiation of clinical trials;
- successful enrollment of patients in, and the completion of, our clinical trials;
- receiving required regulatory authorizations for the development and approvals for the commercialization of our therapeutic candidates;
- establishing and maintaining arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and non-patent exclusivity for our therapeutic candidates and their components;
- enforcing and defending our intellectual property rights and claims;
- achieving desirable therapeutic properties for our therapeutic candidates' intended indications;
- launching commercial sales of our therapeutic candidates, if and when approved, whether alone or in collaboration with third parties;
- acceptance of our therapeutic candidates, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies; and
- maintaining an acceptable safety profile of our therapeutic candidates through clinical trials and following regulatory approval.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our therapeutic candidates, which would materially harm our business.

If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of our therapeutics may be delayed and, as a result, our stock price may decline.

From time to time, we estimate the timing of the anticipated accomplishment of various scientific, clinical, regulatory and other therapeutic development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of scientific studies and clinical trials and the submission of regulatory filings. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are and will be based on numerous assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, or at all, the commercialization of our therapeutics may be delayed or never achieved and, as a result, our stock price may decline.

Our approach to the discovery and development of our therapeutic treatments is based on novel technologies that are unproven and may not result in marketable therapeutics.

We are developing a pipeline of therapeutic candidates using our DELSCAPE platform. Historically, dozens of IL-17A small molecule candidates of other companies that entered late-stage clinical trials have failed to result in FDA, MHRA or the European Medicines Agency ("EMA") approved medicines. We are aware of certain companies currently exploring oral approaches to integrins. Certain development efforts and clinical results of these other companies have in the past, and may be in the future, mixed or unsuccessful, which could result in a negative perception of oral integrins and negatively impact the regulatory approval process of our therapeutic candidates, which would have a material and adverse effect on our business. We believe that therapeutic candidates identified with our platform may offer an optimized therapeutic approach by taking advantage of conformational targeting next-generation physics-based technologies augmented with machine learning and artificial intelligence, which allow us to design, iterate and optimize leads in our discovery process. However, the scientific research that forms the basis of our efforts to develop therapeutic candidates using our platform is ongoing and may not result in viable therapeutic candidates.

To date, we are conducting clinical testing of DC-806 but have not tested any of our other therapeutic candidates in any clinical studies. We may ultimately discover that our DELSCAPE platform and any therapeutic candidates resulting therefrom do not possess certain properties required for therapeutic effectiveness, including the ability to lock specific integrin conformations. Our therapeutic candidates may also be unable to remain stable in the human body for the period of time required for the drug to reach the target tissue or they may trigger immune responses that inhibit the ability of the therapeutic candidate to reach the target tissue or that cause adverse side effects in humans. We currently have only preclinical data regarding oral bioavailability of our therapeutic candidates. We may spend substantial funds attempting to introduce these properties and may never succeed in doing so. In addition, therapeutic candidates based on our platform may demonstrate different chemical and pharmacological properties in patients than they do in laboratory studies. Our platform and any therapeutic candidates resulting therefrom may not demonstrate the same chemical and pharmacological properties in humans and may interact with human biological systems in unforeseen, ineffective or harmful ways.

The regulatory approval process for novel therapeutic candidates such as ours can be more expensive and take longer than for other, better known or extensively studied therapeutic candidates. To our knowledge, no regulatory authority has granted approval for an oral small-molecule integrin inhibitor. We believe the FDA and the MHRA have limited experience with oral integrin-based therapeutics, which may increase the complexity, uncertainty and length of the regulatory approval process for our therapeutic candidates. We and our existing or future collaborators may never receive approval to market and commercialize any therapeutic candidate. Even if we or an existing or future collaborator obtains regulatory approval, the approval may be for targets, disease indications or patient populations that are not as broad as we intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. We or an existing or future collaborator may be required to perform additional or unanticipated clinical trials to obtain approval or be subject to post-marketing testing requirements to maintain regulatory approval. If the therapeutics resulting from our DELSCAPE platform and research programs prove to be ineffective, unsafe or commercially unviable, our platform and pipeline would have little, if any, value, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

Preclinical and clinical development involve a lengthy and expensive process, with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our current therapeutic candidates or any future therapeutic candidates.

We only recently began dosing in our Phase 1 clinical trial for our lead therapeutic candidate, DC-806, and all of our other therapeutic candidates are in preclinical development and their risk of failure is high. It is impossible to predict when or if any of our therapeutic candidates, including DC-806, will receive regulatory approval. To obtain the requisite regulatory approvals to commercialize any therapeutic candidates, we must demonstrate through extensive preclinical studies and lengthy, complex and expensive clinical trials that our therapeutic candidates are safe and effective in humans. Clinical testing can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our therapeutic candidates may not be predictive of the results of later-stage clinical trials. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful, and a clinical trial can fail at any stage of testing. Differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their therapeutic candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of their therapeutics. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or to unfavorable safety profiles, notwithstanding promising results in earlier trials. There is typically a high rate of failure of therapeutic candidates proceeding through clinical trials. Most therapeutic candidates that commence clinical trials are never approved as therapeutics and there can be no assurance that any of our current or future clinical trials will ultimately be successful or support clinical development of our current or any of our future therapeutic candidates.

Our lead program targets the IL-17 pathway. Our CTA for our lead therapeutic candidate, DC-806, was approved in September 2021 and our Phase 1 clinical trial commenced in October 2021, and we intend to advance related compounds in the IL-17 program, toward CTA submissions in the future. Commencing our future clinical trials is subject to finalizing the trial design and submitting a CTA to the MHRA or a similar submission to the FDA or a similar foreign regulatory authority. Even after we submit our CTA or comparable submissions in other jurisdictions, the MHRA, the FDA or other regulatory authorities could disagree that we have satisfied their requirements to commence our clinical trials or disagree with our study design, which may require us to complete additional preclinical studies or amend our protocols or impose stricter conditions on the commencement of clinical trials.

We or our collaborators may experience delays in initiating or completing clinical trials. We or our collaborators also may experience numerous unforeseen events during, or as a result of, any current or future clinical trials that we could conduct that could delay or prevent our ability to receive marketing approval or commercialize our lead therapeutic candidate, DC-806, fast follower therapeutic candidate, DC-853, and related compounds in the IL-17 program or any future therapeutic candidates, including:

- regulators such as the MHRA or the FDA or institutional review boards (“IRBs”), or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations (“CROs”) the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- clinical trials of any therapeutic candidates may fail to show safety or efficacy, produce negative or inconclusive results and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or we may decide to abandon product development programs;
- the number of subjects required for clinical trials of any therapeutic candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or subjects may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;

- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- we may elect to, or regulators, IRBs or ethics committees may require that we or our investigators, suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants in our trials are being exposed to unacceptable health risks;
- the cost of clinical trials of any of our therapeutic candidates may be greater than we anticipate;
- the quality of our therapeutic candidates or other materials necessary to conduct clinical trials of our therapeutic candidates may be inadequate to initiate or complete a given clinical trial;
- our inability to manufacture sufficient quantities of our therapeutic candidates for use in clinical trials;
- reports from clinical testing of other therapies may raise safety or efficacy concerns about our therapeutic candidates;
- our failure to establish an appropriate safety profile for a therapeutic candidate based on clinical or preclinical data for such therapeutic candidate as well as data emerging from other molecules in the same class as our therapeutic candidate; and
- the MHRA, FDA, EMA or other regulatory authorities may require us to submit additional data such as long-term toxicology studies, or impose other requirements before permitting us to initiate a clinical trial.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the number and location of clinical sites we enroll, the proximity of patients to clinical sites, the eligibility and exclusion criteria for the trial, the design of the clinical trial, the inability to obtain and maintain patient consents, the risk that enrolled participants will drop out before completion, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the therapeutic candidate being studied in relation to other available therapies, including any new drugs or therapeutic biologics that may be approved for the indications being investigated by us. Furthermore, we expect to rely on our collaborators, CROs and clinical trial sites to ensure the proper and timely conduct of our current and future clinical trials, including the patient enrollment process, and we have limited influence over their performance. Additionally, we could encounter delays if treating clinicians encounter unresolved ethical issues associated with enrolling patients in current or future clinical trials of our therapeutic candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles.

We could also encounter delays if a clinical trial is suspended, put on clinical hold or terminated by us, the IRBs of the institutions in which such trials are being conducted, or the MHRA, FDA, EMA or other regulatory authorities, or if a clinical trial is recommended for suspension or termination by the Data Safety Monitoring Board, or the DSMB, for such trial. A suspension or termination may be imposed due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the MHRA, FDA, EMA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product or treatment, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Clinical studies may also be delayed or terminated as a result of ambiguous or negative interim results. 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 therapeutic candidates. Further, the MHRA, FDA, EMA or other regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials.

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

candidates and harming our business and results of operations. Any delays in our clinical development programs may harm our business, financial condition and results of operations significantly.

The COVID-19 pandemic could adversely impact our business, including our ongoing and anticipated future clinical trials, supply chain and business development activities.

As the COVID-19 pandemic continues around the globe, and if new COVID-19 variants emerge, we may experience disruptions that could severely impact our business and clinical trials, including but not limited to:

- interruption or delays in our operations and/or our external vendor operations, which may impact our ability to conduct and produce preclinical results required for submission of a CTA or IND;
- delays in receiving approval from local regulatory authorities, ethics committees, and/or IRBs to initiate our planned clinical trials;
- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials, including interruption in global shipping that may affect the transport of clinical trial materials;
- changes in local regulations as part of a response to the COVID-19 pandemic or other epidemic diseases which may require us to change the ways in which our planned clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as but not limited to clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;
- interruption or delays in the operations of the MHRA, FDA, EMA or other regulatory authorities, which may impact review and approval timelines;
- risk that participants enrolled in our clinical trials will acquire COVID-19 or other epidemic disease while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- disruptions in supply of key reagents which we rely upon for our therapeutic candidates, the absence of which may delay our clinical trials; and
- refusal of the FDA to accept data from clinical trials in affected geographies.

These and other disruptions in our operations and the global economy could negatively impact our business, operating results and financial condition.

The spread of COVID-19 and its variants and actions taken to reduce its spread may also materially affect us economically. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, there could be a significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity and financial position. In addition, the trading prices for other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock or such sales may be on unfavorable terms.

COVID-19 and actions taken to reduce its spread continue to rapidly evolve. The extent to which COVID-19 may impede the development of our therapeutic candidates, reduce the productivity of our employees, disrupt our supply chains, delay our clinical trials, reduce our access to capital or limit our business development activities, will depend

on future developments, which are highly uncertain and cannot be predicted with confidence. To the extent the COVID-19 pandemic or other epidemic diseases adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this "Risk Factors" section.

Results of preclinical studies and early clinical trials on any of our therapeutic candidates may not be predictive of results of future clinical trials.

The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier development, and we could face similar setbacks. The design of a clinical trial can determine whether its results will support approval of a therapeutic, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their therapeutic candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for the therapeutic candidates. Even if we, or future collaborators, believe that the results of clinical trials for our therapeutic candidates warrant marketing approval, the MHRA, FDA, EMA or comparable foreign regulatory authorities may disagree and may not grant marketing approval of our therapeutic candidates.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same therapeutic candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial patients. If we fail to receive positive results in clinical trials of our therapeutic candidates, the development timeline and regulatory approval and commercialization prospects for our most advanced therapeutic candidates, and, correspondingly, our business and financial prospects would be negatively impacted.

Preliminary, interim or topline data from our 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 preliminary, interim or topline data from our preclinical studies and clinical trials, which is based on an 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. Further, modifications or improvements to our manufacturing processes for a therapy may result in changes to the characteristics or behavior of the therapeutic candidate that could cause our therapeutic candidates to perform differently and affect the results of our ongoing clinical trials. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available.

From time to time, we may also disclose preliminary data from or data from planned interim analysis of our preclinical studies and clinical trials. Preliminary or interim data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Additionally, disclosure of preliminary or interim data by us or by our competitors could result in volatility in the price of our common stock. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions, or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular therapeutic candidate and our company in general. If the preliminary, interim, or topline 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, any of our potential therapeutic candidates may be harmed, which could harm our business, operating results, prospects, or financial condition.

Our current and future clinical trials or those of our future collaborators may reveal significant adverse events not seen in our preclinical studies and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our therapeutic candidates.

If significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to such trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of one or more therapeutic candidates altogether. For example, certain drugs targeting the IL-17 pathway have been linked to gastrointestinal distress. We, the MHRA, FDA, EMA or other applicable regulatory authorities, or an IRB may suspend any clinical trials of any therapeutic candidate at any time for various reasons, including a belief that subjects or patients in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the therapeutic candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of the approved therapeutic due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition and prospects.

We may not be successful in our efforts to use our DELSCAPE platform to expand our pipeline of therapeutic candidates and develop marketable therapeutics.

The success of our business depends in part upon our ability to discover, develop and commercialize therapeutics based on our DELSCAPE platform. IL-17 is our lead program and our research program may fail to identify other potential therapeutic candidates for clinical development for a number of reasons. Our research methodology may be unsuccessful in identifying potential therapeutic candidates or our potential therapeutic candidates may be shown to have harmful side effects or may have other characteristics that may make the therapeutics unmarketable or unlikely to receive marketing approval. If any of these events occur, we may be forced to abandon our development efforts for a program or for multiple programs, which would materially harm our business and could potentially cause us to cease operations. Research programs to identify new therapeutic candidates require substantial technical, financial and human resources.

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

Because we have limited financial and managerial resources, we focus our research and development efforts on certain selected therapeutic candidates. For example, we are initially focused on our lead therapeutic candidate, DC-806, fast follower therapeutic candidate, DC-853, and related compounds in the IL-17 program. As a result, we may forgo or delay pursuit of opportunities with other therapeutic candidates 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 therapeutic candidates for specific indications may not yield any commercially viable therapeutic candidates. If we do not accurately evaluate the commercial potential or target market for a particular therapeutic candidate, we may relinquish valuable rights to that therapeutic 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 therapeutic candidate.

We face competition from entities that have developed or may develop therapeutic candidates for the diseases addressed by our therapeutic candidates, including companies developing novel treatments and technology platforms. If these companies develop technologies or therapeutic candidates more rapidly than we do or their technologies are more effective, our ability to develop and successfully commercialize therapeutic candidates may be adversely affected.

The development and commercialization of drugs is highly competitive. Our therapeutic candidates, if approved, will face significant competition and our failure to effectively compete may prevent us from achieving significant

market penetration. Most of our competitors have significantly greater resources than we do, and we may not be able to successfully compete. We compete with a variety of multinational biopharmaceutical companies, specialized biotechnology companies and emerging biotechnology companies, as well as with technologies and therapeutic candidates being developed at universities and other research institutions. Our competitors have developed, are developing or will develop therapeutic candidates and processes competitive with our therapeutic candidates and processes. Competitive therapeutic treatments include those that have already been approved and accepted by the medical community and any new treatments, including those based on novel technology platforms that enter the market. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of conditions for which we are trying, or may try, to develop therapeutic candidates. There is intense and rapidly evolving competition in the biotechnology, biopharmaceutical and integrin and immunoregulatory therapeutics fields. Competition from many sources exists or may arise in the future. Our competitors include larger and better funded biopharmaceutical, biotechnological and therapeutics companies, including companies focused on therapeutics for autoimmune, cardiovascular and metabolic diseases, fibrosis and cancer, as well as numerous small companies. Moreover, we also compete with current and future therapeutics developed at universities and other research institutions. Some of these companies are well-capitalized and, in contrast to us, have significant clinical experience, and may include our existing or future collaborators. In addition, these companies compete with us in recruiting scientific and managerial talent.

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

Our IL-17 program, initially under development for treatment of psoriasis, if approved would face competition from approved psoriasis treatments marketed by Novartis and Amgen, in addition to other major pharmaceutical companies.

Many of these competitors have significantly greater financial, technical, manufacturing, marketing, sales, and supply resources or experience than we have. If we successfully obtain approval for any therapeutic candidate, we will face competition based on many different factors, including the safety and effectiveness of our therapeutics, the ease with which our therapeutics can be administered and the extent to which patients accept relatively new routes of administration, the timing and scope of regulatory approvals for these therapeutics, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Competing therapeutics could present superior treatment alternatives, including by being more effective, safer, less expensive or marketed and sold more effectively than any therapeutics we may develop. Competitive therapeutics may make any therapeutics we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our therapeutic candidates. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan.

Our current therapeutic candidates or any future therapeutic candidates may not achieve adequate market acceptance among clinicians, patients, healthcare third-party payors and others in the medical community necessary for commercial success, if approved, and we may not generate any future revenue from the sale or licensing of therapeutic candidates.

Even if regulatory approval is obtained for a therapeutic candidate, we may not generate or sustain revenue from sales of the therapeutic due to factors such as whether the therapeutic can be sold at a competitive cost and whether it will otherwise be accepted in the market. Historically, several injectable disruptive proteins have been approved by the FDA for treatment of psoriasis. However, our lead therapeutic candidate is a small molecule with the potential to modulate protein-protein interactions as effectively as systemic biologics; to date, such no oral small molecule has been approved by the FDA. Market participants with significant influence over acceptance of new treatments, such as clinicians and third-party payors, may not adopt an orally bioavailable product based on our novel technologies, and we may not be able to convince the medical community and third-party payors to accept and use, or to provide favorable reimbursement for, any therapeutic candidates developed by us or our existing or future collaborators. Market acceptance of our therapeutic candidates will depend on, among other factors:

- the timing of our receipt of any marketing and commercialization approvals;

- the terms of any approvals and the countries in which approvals are obtained;
- the safety and efficacy of our therapeutic candidates as demonstrated in any current or future clinical trials;
- the prevalence and severity of any adverse side effects associated with our therapeutic candidates;
- limitations or warnings contained in any labeling approved by the MHRA, the FDA or any other regulatory authority;
- relative convenience and ease of administration of our therapeutic candidates;
- the willingness of patients to accept any new methods of administration;
- unfavorable publicity relating to our current therapeutic candidates or any future therapeutic candidates;
- the success of our physician education programs;
- the effectiveness of sales and marketing efforts;
- the availability of coverage and adequate reimbursement from government and third-party payors;
- the pricing of our therapeutics, particularly as compared to alternative treatments; and
- the availability of alternative effective treatments for the disease indications our therapeutic candidates are intended to treat and the relative risks, benefits and costs of those treatments.

Sales of medical products also depend on the willingness of clinicians to prescribe the treatment, which is likely to be based on a determination by these clinicians that the products are safe, therapeutically effective and cost effective. In addition, the inclusion or exclusion of products from treatment guidelines established by various physician groups and the viewpoints of influential clinicians can affect the willingness of other clinicians to prescribe the treatment. We cannot predict whether clinicians, clinicians' organizations, hospitals, other healthcare providers, government agencies or private insurers will determine that our therapeutic is safe, therapeutically effective and cost effective as compared with competing treatments. If any current or future therapeutic candidate is approved but does not achieve an adequate level of acceptance by such parties, we may not generate or derive sufficient revenue from that therapeutic candidate and may not become or remain profitable.

Because our therapeutic candidates are based on new technology, we expect that they will require extensive research and development and have substantial manufacturing and processing costs. In addition, our estimates regarding potential market size for any indication may be materially different from what we discover to exist at the time we commence commercialization, if any, for a therapeutic, which could result in significant changes in our business plan and have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if any therapeutic candidate we commercialize fails to achieve market acceptance, it could have a material and adverse effect on our business, financial condition, results of operations and prospects.

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

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

- the patient eligibility and exclusion criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints and the process for identifying patients;
- the willingness or availability (including legality under applicable COVID-19 shelter-in-place regulations) of patients to participate in our trials (including due to fears of contracting COVID-19);
- the proximity of patients to trial sites;

- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages and risks of the therapeutic candidate being studied in relation to other available therapies, including any new therapeutics that may be approved for the indications we are investigating;
- the availability of competing commercially available therapies and other competing therapeutic candidates' clinical trials;
- our ability to obtain and maintain patient informed consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

Further, timely enrollment in clinical trials is reliant on clinical trial sites which may be adversely affected by global health matters, including, among other things, pandemics. For example, our clinical trial sites have been affected by the COVID-19 pandemic. If patients are unable to follow the trial protocols or if our trial results are otherwise disputed due to the effects of the COVID-19 pandemic or actions taken to mitigate its spread, the integrity of data from our trials may be compromised or not accepted by the FDA or other regulatory authorities, which would represent a significant setback for the applicable program.

If in the future we are unable to establish U.S., UK or global sales and marketing capabilities or enter into agreements with third parties to sell and market our therapeutic candidates, we may not be successful in commercializing our therapeutic candidates if they are approved and we may not be able to generate any revenue.

We currently do not have a marketing or sales team for the marketing, sales and distribution of any of our current or future therapeutic candidates that are able to obtain regulatory approval. To commercialize any therapeutic candidates after approval, we must build on a territory-by-territory basis marketing, sales, distribution, managerial and other non-technical capabilities or arrange with third parties to perform these services, and we may not be successful in doing so. If our therapeutic candidates receive regulatory approval, we may decide to establish an internal sales or marketing team with technical expertise and supporting distribution capabilities to commercialize any of our current or future therapeutic candidates, which will be expensive and time consuming and will require significant attention of our current or future executive officers to manage. For example, some state and local jurisdictions have licensing and continuing education requirements for pharmaceutical sales representatives, which requires time and financial resources. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of any of our current or future therapeutic candidates that we obtain approval to market.

With respect to the commercialization of all or certain of our therapeutic candidates, we may choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements when needed on acceptable terms, or at all, we may not be able to successfully commercialize any of our current or future therapeutic candidates that receive regulatory approval or any such commercialization may experience delays or limitations. If we are not successful in commercializing our current or future therapeutic candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer, and we may incur significant additional losses.

If any of our current or future therapeutic candidates receives marketing approval and we or others later identify undesirable side effects caused by such therapeutic candidate, our ability to market and derive revenue from such therapeutic candidates could be compromised.

Undesirable side effects caused by our therapeutic candidates could cause regulatory authorities to interrupt, delay or halt clinical trials and could result in more restrictive labeling or the delay or denial of regulatory approval by the MHRA, FDA, EMA or other regulatory authorities. Results of current or future clinical trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, our current or future clinical trials could be suspended or terminated and the MHRA, FDA, EMA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our therapeutic candidates for any or all targeted indications. Such

side effects could also affect patient recruitment or the ability of enrolled patients to initiate or complete the clinical trial or result in potential product liability claims. Any of these occurrences may materially and adversely affect our business, financial condition, results of operations, prospects and our ability to raise capital.

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

In the event that any of our current or future therapeutic candidates receive regulatory approval and we or others identify undesirable side effects caused by such therapeutic, any of the following adverse events could occur:

- regulatory authorities may withdraw their approval of the therapeutic or seize the therapeutic;
- we may be required to recall the therapeutic or change the way the therapeutic is administered to patients;
- additional restrictions may be imposed on the marketing of the particular therapeutic or the manufacturing processes for the therapeutic or any component thereof;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of labeling statements, 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 implement a REMS, which may impose further requirements or restrictions on the distribution or use of our therapeutic candidates;
- we could be sued and held liable for harm caused to patients;
- the therapeutic may become less competitive; and
- our reputation may suffer.

Any of these occurrences could have a material and adverse effect on our business, financial condition, results of operations and prospects.

We anticipate that some of our current or future therapeutic candidates may be studied in combination with third-party drugs, some of which may still be in development, and we have limited or no control over the supply, regulatory status, or regulatory approval of such drugs.

Some of our current or future therapeutic candidates may be studied in combination with third-party drugs. For example, we may explore the use of our oral disruptive protein-protein therapeutics targeting IL-17 as a combination therapy with other drugs for the treatment of psoriasis. The development of therapeutic candidates for use in combination with another therapeutic candidate may present challenges that are not faced for single agent therapeutic candidates. The MHRA, FDA, EMA or other regulatory authorities may require us to use more complex clinical trial designs in order to evaluate the contribution of each therapeutic candidate to any observed effects. It is possible that the results of these trials could show that any positive previous trial results are attributable to the combination therapy and not our lead therapeutic candidate. Moreover, following product approval, the MHRA, FDA, EMA or other regulatory authorities may require that products used in conjunction with each other be cross labeled for combined use. To the extent that we do not have rights to the other product, this may require us to work with a third party to satisfy such a requirement. Moreover, developments related to the other product may impact our future clinical trials for the combination as well as our commercial prospects should we receive marketing approval. Such developments may include changes to the other product's safety or efficacy profile, changes to the availability of the approved product, and changes to the standard of care.

If we pursue such combination therapies, we cannot be certain that a steady supply of such drugs will be commercially available. Any failure to enter into such commercial relationships, or the expense of purchasing therapies in the market, may delay our development timelines, increase our costs and jeopardize our ability to

develop our therapeutic candidates as commercially viable combination therapies. The occurrence of any of these could adversely affect our business, results of operations and financial condition.

In the event that any future collaborator or supplier cannot continue to supply their products on commercially reasonable terms, we would need to identify alternatives for accessing such products. Additionally, should the supply of products of any collaborator or supplier be interrupted, delayed or otherwise be unavailable to us, our clinical trials may be delayed. In the event we are unable to source a supply of any alternative therapy, or are unable to do so on commercially reasonable terms, our business, results of operations and financial condition may be adversely affected.

Risks Related to Our Reliance on Third Parties

We have historically entered into collaborations and may, in the future, seek to enter into collaborations with third parties for the discovery, development and commercialization of our therapeutic candidates. If our future collaborators cease development efforts under collaboration agreements, or if those agreements are terminated, the collaborations may fail to lead to commercial products, and we may never receive milestone payments or future royalties under the agreements.

We may in the future seek third-party collaborators for research, development and commercialization of other therapeutic technologies or therapeutic candidates. Biopharmaceutical companies are our prior and likely future collaborators for any marketing, distribution, development, licensing or broader collaboration arrangements. If we fail to enter into future collaborations on commercially reasonable terms, or at all, or such collaborations are not successful, we may not be able to execute our strategy to develop certain targets, therapeutic candidates or disease areas that we believe could benefit from the resources of either larger biopharmaceutical companies or those specialized in a particular area of relevance.

With respect to any future collaboration agreements, we expect to have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our current or future therapeutic candidates. Moreover, our ability to generate revenue from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving our current or future therapeutic candidates currently pose, and will continue to pose, the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not pursue development and commercialization of our therapeutic candidates or may elect not to continue or renew development or commercialization programs based on preclinical studies or clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a therapeutic candidate, repeat or conduct new clinical trials or require a new formulation of a therapeutic candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our current or future therapeutic candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- collaborators with marketing and distribution rights to one or more therapeutics may not commit sufficient resources to the marketing and distribution of such therapeutic or therapeutics;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to litigation or potential liability;

- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our current or future therapeutic candidates or that result in costly litigation or arbitration that diverts management attention and resources; and
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable therapeutic candidates.

As a result of the foregoing, any future collaboration agreements may not lead to development or commercialization of our therapeutic candidates in the most efficient manner or at all. If a current or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our current or future product development or commercialization program could be delayed, diminished or terminated. Any failure to successfully develop or commercialize our therapeutic candidates pursuant to our current or any future collaboration agreements could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Moreover, to the extent that any future collaborators were to terminate a collaboration agreement, we may be forced to independently develop these therapeutic candidates, including funding preclinical studies or clinical trials, assuming marketing and distribution costs and defending intellectual property rights, or, in certain instances, abandon therapeutic candidates altogether, any of which could result in a change to our business plan and have a material adverse effect on our business, financial condition, results of operations and prospects.

We may have conflicts with future collaborators that could delay or prevent the development or commercialization of our therapeutic candidates.

We may have conflicts with future collaborators, such as conflicts concerning the interpretation of preclinical or clinical data, the achievement of milestones, the interpretation of contractual obligations, payments for services, development obligations or the ownership of intellectual property developed during our collaboration. If any conflicts arise with any of our collaborators, such collaborator may act in a manner that is adverse to our best interests. Any such disagreement could result in one or more of the following, each of which could delay or prevent the development or commercialization of our therapeutic candidates, and in turn prevent us from generating revenue: unwillingness on the part of a collaborator to pay us milestone payments or royalties we believe are due to us under a collaboration, which could require us to raise additional capital; uncertainty regarding ownership of intellectual property rights arising from our collaborative activities, which could prevent us from entering into additional collaborations; unwillingness by the collaborator to cooperate in the development or manufacture of the therapeutic, including providing us with therapeutic data or materials; unwillingness on the part of a collaborator to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities; initiating of litigation or alternative dispute resolution options by either party to resolve the dispute; or attempts by either party to terminate the agreement.

We may not successfully engage in strategic transactions, including any collaborations we seek, which could adversely affect our ability to develop and commercialize therapeutic candidates, impact our cash position, increase our expenses and present significant distractions to our management.

From time to time, we may consider strategic transactions, such as collaborations, acquisitions of companies, asset purchases and out- or in-licensing of therapeutic candidates or technologies that we believe will complement or augment our existing business. In particular, we will evaluate and, if strategically attractive, seek to enter into collaborations, including with major biotechnology or biopharmaceutical companies. The competition for collaborators is intense, and the negotiation process is time-consuming and complex. Any new collaboration may be on terms that are not optimal for us, and we may not be able to maintain any new collaboration if, for example, development or approval of a therapeutic candidate is delayed, sales of an approved therapeutic candidate do not meet expectations or the collaborator terminates the collaboration. In addition, a significant number of recent business combinations among large pharmaceutical companies has resulted in a reduced number of potential future strategic partners. Our collaborators may consider alternative therapeutic candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than

the one with us for our therapeutic candidate. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the strategic partner's resources and expertise, the terms and conditions of the proposed collaboration and the proposed strategic partner's evaluation of a number of factors. These factors may include the design or results of clinical trials, the likelihood of approval by the MHRA, FDA, EMA or similar regulatory authorities outside the United States, the potential market for the subject therapeutic candidate, the costs and complexities of manufacturing and delivering such therapeutic candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. Moreover, if we acquire assets with promising markets or technologies, we may not be able to realize the benefit of acquiring such assets if we are not able to successfully integrate them with our existing technologies. We may encounter numerous difficulties in developing, testing, manufacturing and marketing any new products resulting from a strategic acquisition that delay or prevent us from realizing their expected benefits or enhancing our business.

We cannot assure you that following any such collaboration, or other strategic transaction, we will achieve the expected synergies to justify the transaction. For example, such transactions may require us to incur non-recurring or other charges, increase our near- and long-term expenditures and pose significant integration or implementation challenges or disrupt our management or business. These transactions would entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention in order to manage a collaboration or develop acquired products, therapeutic candidates or technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business.

Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks and would have a material and adverse effect on our business, financial condition, results of operations and prospects. Conversely, any failure to enter any additional collaboration or other strategic transaction that would be beneficial to us could delay the development and potential commercialization of our current or future therapeutic candidates and have a negative impact on the competitiveness of any therapeutic candidate that reaches market.

In addition, the anticipated benefit of any strategic alliance, joint venture or acquisition may not materialize or such strategic alliance, joint venture or acquisition may be prohibited. In April 2021, we entered into the SVB Loan and Security Agreement with SVB, which restricts our ability to pursue certain mergers and acquisitions, that we may believe to be in our best interest. Additionally, future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write-offs of goodwill, any of which could harm our financial condition. We cannot predict the number, timing or size of future joint ventures or acquisitions, or the effect that any such transactions might have on our operating results.

We rely and expect to continue to rely on third parties to conduct certain of our preclinical studies or clinical trials. If those third parties do not perform as contractually required, fail to satisfy legal or regulatory requirements, miss expected deadlines or terminate the relationship, our development program could be delayed with potentially material and adverse effects on our business, financial condition, results of operations and prospects.

We rely and intend to rely in the future on third-party clinical investigators, CROs, clinical data management organizations and consultants to assist or provide the design, conduct, supervision and monitoring of preclinical studies and any current or future clinical trials of our current or future therapeutic candidates. Because we currently rely and intend to continue to rely on these third parties and will not have the ability to conduct all preclinical studies or clinical trials independently, we will have less control over the timing, quality and other aspects of preclinical studies and clinical trials than we would have had we conducted them on our own. These investigators, CROs and consultants will not be our employees and we will have limited control over the amount of time and resources that they dedicate to our programs. These third parties may have contractual relationships with other entities, some of

which may be our competitors, which may draw time and resources from our programs. The third parties with which we may contract might not be diligent, careful or timely in conducting our preclinical studies or clinical trials, resulting in the preclinical studies or clinical trials being delayed or unsuccessful.

If we cannot contract with acceptable third parties on commercially reasonable terms, or at all, or if these third parties do not carry out their contractual duties, satisfy legal and regulatory requirements for the conduct of preclinical studies or clinical trials or meet expected deadlines, our clinical development programs could be delayed and otherwise adversely affected. In all events, we will be responsible for ensuring that each of our preclinical studies and clinical trials are conducted in accordance with the general investigational plan and protocols for the trial as well as applicable legal and regulatory requirements. The MHRA and the FDA generally require preclinical studies to be conducted in accordance with good laboratory practices and clinical trials to be conducted in accordance with good clinical practices, including for designing, conducting, recording and reporting the results of preclinical studies and clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. Our reliance on third parties that we do not control will not relieve us of these responsibilities and requirements. Any adverse development or delay in our preclinical studies or clinical trials as a result of our reliance on third parties could have a material and adverse effect on our business, financial condition, results of operations and prospects.

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

We rely on third-party manufacturers and suppliers to supply components of our therapeutic candidates. The loss of our third-party manufacturers or suppliers, or their failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect our business.

We do not own or operate facilities for drug manufacturing, storage, distribution or quality testing. We currently rely, and may continue to rely, on third-party contract manufacturers, including in the UK and China, to manufacture bulk drug substances, drug products, raw materials, samples, components, or other materials and reports. Reliance on third-party manufacturers may expose us to different risks than if we were to manufacture therapeutic candidates ourselves. There can be no assurance that our preclinical and clinical development product supplies will not be limited, interrupted, terminated or of satisfactory quality or continue to be available at acceptable prices. For example, rhodium, a reagent we use in our studies, has recently been in short supply, resulting in increased purchasing costs. In addition, any replacement of our manufacturer could require significant effort and expertise because there may be a limited number of qualified replacements.

The manufacturing process for a therapeutic candidate is subject to MHRA, FDA, EMA and foreign regulatory authority review. We, and our suppliers and manufacturers, some of which are currently our sole source of supply, must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as current Good Manufacturing Practices (“cGMPs”). Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the MHRA, FDA, EMA and foreign regulatory authorities. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the MHRA, FDA, EMA comparable foreign regulatory authorities, we may not be able to rely on their manufacturing facilities for the manufacture of elements of our therapeutic candidates. Moreover, we do not control the manufacturing process at our contract manufacturers and are completely dependent on them for compliance with current regulatory requirements. In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to enter into an agreement with another third party, which we may not be able to do on reasonable terms, if at all. In some cases, the technical skills or technology required to manufacture our therapeutic candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such to another third party.

These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to enable us, or to have another third party, manufacture our therapeutic candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines; and we may be required to repeat some of the development program. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop therapeutic candidates in a timely manner or within budget.

We expect to continue to rely on third-party manufacturers if we receive regulatory approval for any therapeutic candidate. To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. Any manufacturing facilities used to produce our therapeutics will be subject to periodic review and inspection by the MHRA, or the FDA and foreign regulatory authorities, including for continued compliance with cGMP requirements, quality control, quality assurance and corresponding maintenance of records and documents. If we are unable to obtain or maintain third-party manufacturing for therapeutic candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our therapeutic candidates successfully. Our or a third party's failure to execute on our manufacturing requirements, comply with cGMPs or maintain a compliance status acceptable to the MHRA, FDA, EMA or foreign regulatory authorities could adversely affect our business in a number of ways, including:

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

Additionally, our contract manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our contract manufacturers were to encounter any of these difficulties, our ability to provide our therapeutic candidates to patients in preclinical and clinical trials, or to provide product for treatment of patients once approved, would be jeopardized.

For example, the UK formally left the EU on January 31, 2020, often referred to as Brexit, and the transition period ended on December 31, 2020. Brexit has caused uncertainty in the current regulatory framework in Europe. For instance, Brexit has resulted in the European Medicines Agency, or the EMA, moving from the UK to the Netherlands. In the UK, Brexit may cause disruption in the administrative and medical scientific links between the EMA and MHRA. On December 31, 2020, the UK passed legislation giving effect to the trade and cooperation agreement, which the EU ratified in April 2021. The trade and cooperation agreement entered into force in May 2021. The trade and cooperation agreement sets out certain procedures for approval and recognition of medical products in each jurisdiction. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of the trade and cooperation agreement or otherwise, could prevent us from commercializing any therapeutic candidates in the UK and/or the EU and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the UK and/or EU for any therapeutic candidates, which could significantly and materially harm our business. The current lack of detail and resolution with regard to the Brexit implementation may result in a disruption of the manufacturing and supply of components of our therapeutic candidates in the UK and we are unable to confidently predict the effects of such disruption to the regulatory framework in Europe. Any adjustments we make to our business and operations as a result of Brexit could result in significant delays and additional expense. Any of the foregoing factors could have a material adverse effect on our business, results of operations, or financial condition.

Changes in methods of therapeutic candidate manufacturing or formulation may result in additional costs or delay.

As therapeutic candidates progress through preclinical and clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our therapeutic candidates to perform differently and affect the results of current or future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our therapeutic candidates and jeopardize our ability to commercialize our therapeutic candidates, if approved, and generate revenue.

The manufacturing of our small molecules is complex, and our third-party manufacturers may encounter difficulties in production. If we or any of our third-party manufacturers encounter such difficulties, our ability to provide supply of our therapeutic candidates for clinical trials, our ability to obtain marketing approval, or our ability to provide supply of our therapeutics for patients, if approved, could be delayed or stopped.

Our therapeutic candidates are biopharmaceuticals and the process of manufacturing biopharmaceuticals is complex, time-consuming, highly regulated and subject to multiple risks. Our contract manufacturers must comply with legal requirements, cGMPs and guidelines for the manufacturing of biopharmaceuticals used in clinical trials and, if approved, marketed therapeutics. Our contract manufacturers may have limited experience in the manufacturing of cGMP batches.

Manufacturing biopharmaceuticals is highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered at our third-party manufacturers' facilities, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business. Moreover, if the MHRA or the FDA determines that our third-party manufacturers' facilities are not in compliance with MHRA or the FDA laws and regulations, including those governing cGMPs, the MHRA or the FDA, as applicable, may deny NDA approval, respectively, until the deficiencies are corrected or we replace the manufacturer in our NDA with a manufacturer that is in compliance.

In addition, there are risks associated with large scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with cGMPs, lot consistency and timely availability of raw materials. Even if our collaborators obtain regulatory approval for any of our therapeutic candidates, there is no assurance that manufacturers will be able to manufacture the approved product to specifications acceptable to the MHRA, FDA, EMA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and prospects.

Scaling up a biopharmaceutical manufacturing process is a difficult and uncertain task, and our third-party manufacturers may not have the necessary capabilities to complete the implementation, manufacturing and development process. If we are unable to adequately validate or scale-up the manufacturing process at our current manufacturers' facilities, we will need to transfer to another manufacturer and complete the manufacturing validation process, which can be lengthy. If we are able to adequately validate and scale-up the manufacturing process for our therapeutic candidates with a contract manufacturer, we will still need to negotiate with such contract manufacturer an agreement for commercial supply and it is not certain we will be able to come to agreement on terms acceptable to us.

We cannot assure you that any stability or other issues relating to the manufacture of any of our current or future therapeutic candidates or products will not occur in the future. If our third-party manufacturers were to encounter any of these difficulties, our ability to provide any therapeutic candidates to patients in planned clinical trials and products to patients, once approved, would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of planned clinical trials, increase the costs associated with maintaining clinical

trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely. Any adverse developments affecting clinical or commercial manufacturing of our therapeutic candidates or products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our therapeutic candidates or products. We may also have to take inventory write-offs and incur other charges and expenses for therapeutic candidates or products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Accordingly, failures or difficulties faced at any level of our supply chain could adversely affect our business and delay or impede the development and commercialization of any of our therapeutic candidates or products, if approved, and could have an adverse effect on our business, prospects, financial condition and results of operations.

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

Risks Related to Our Business and Operations

We will need to grow our organization, and we may experience difficulties in managing our growth and expanding our operations, which could adversely affect our business.

As of March 31, 2022, we had 56 full-time employees. As our development and commercialization plans and strategies develop, and as we transition into operating as a public company, we expect to expand our employee base for managerial, operational, financial and other resources. In addition, we have limited experience in product development. As our therapeutic candidates enter and advance through preclinical studies and clinical trials, we will need to expand our development and regulatory capabilities and contract with other organizations to provide manufacturing and other capabilities for us. In the future, we expect to have to manage additional relationships with collaborators or partners, suppliers and other organizations. Our ability to manage our operations and future growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures. We may not be able to implement improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. Our inability to successfully manage our growth and expand our operations could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Any inability to attract and retain qualified key management and technical personnel would impair our ability to implement our business plan.

Our success largely depends on the continued service of key management, advisors and other specialized personnel, including J. Kevin Judice, Ph.D., our founder and chief executive officer. We currently do not maintain key person insurance on these individuals. The loss of one or more members of our management team or other key employees or advisors could delay our research and development programs and have a material and adverse effect on our business, financial condition, results of operations and prospects. The relationships that our key managers have cultivated within our industry make us particularly dependent upon their continued employment with us. We are dependent on the continued service of our technical personnel, in particular, personnel involved with disrupting protein-protein interactions, because of the highly technical nature of our therapeutic candidates and technologies related to our DELSCAPE platform, and the specialized nature of the regulatory approval process. Because our management team and key employees are not obligated to provide us with continued service, they could terminate their employment with us at any time without penalty.

We conduct our operations at our facility in South San Francisco, California. This region is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel

in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. We also face competition for personnel from other companies, universities, public and private research institutions, government entities and other organizations. Our future success will depend in large part on our continued ability to attract and retain other highly qualified scientific, technical and management personnel, as well as personnel with expertise in clinical testing, manufacturing, governmental regulation and commercialization. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover and develop therapeutic candidates will be limited which could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future growth may depend, in part, on our ability to develop and commercialize our therapeutic candidates in foreign markets for which we may rely on collaboration with third parties. We are not permitted to market or promote any of our therapeutic candidates before we receive regulatory approval from the applicable regulatory authority in that foreign market, and may never receive such regulatory approval for any of our therapeutic 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 and governing, among other things, clinical trials and commercial sales, pricing and distribution of our therapeutic candidates, and we cannot predict success in these jurisdictions. If we fail to comply with the regulatory requirements in international markets and receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our therapeutic candidates will be harmed and our business will be adversely affected. We may not obtain foreign regulatory approvals on a timely basis, if at all. Our failure to obtain approval of any of our therapeutic candidates by regulatory authorities in another country may significantly diminish the commercial prospects of that therapeutic candidate and our business, financial condition, results of operations and prospects could be materially and adversely affected. Moreover, even if we obtain approval of our therapeutic candidates and ultimately commercialize our therapeutic candidates in foreign markets, we would be subject to the risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and reduced protection of intellectual property rights in some foreign countries.

Our business entails a significant risk of product liability and our ability to obtain sufficient insurance coverage could have a material and adverse effect on our business, financial condition, results of operations and prospects.

In conducting clinical trials of our current or future therapeutic candidates, we may be exposed to significant product liability risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in an MHRA, FDA, EMA or the investigation of the safety and effectiveness of our future therapeutics, our manufacturing processes and facilities or our marketing programs and potentially a recall of our therapeutics or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our therapeutics, termination of clinical trial sites or entire trial programs, withdrawal of clinical trial participants, injury to our reputation and significant negative media attention, significant costs to defend the related litigation, a diversion of management's time and our resources from our business operations, substantial monetary awards to trial participants or patients, loss of revenue, the inability to commercialize and products that we may develop, and a decline in our stock price. We currently maintain general liability insurance with coverage up to $2 million per occurrence. We may, however, need to obtain higher levels of product liability insurance for later stages of clinical development or marketing any of our therapeutic candidates. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have a material and adverse effect on our business, financial condition, results of operations and prospects.

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

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with MHRA or FDA, respectively, regulations, provide true, complete and accurate information to the MHRA, FDA, EMA and other similar foreign regulatory bodies, comply with manufacturing standards we may establish, comply with healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. If we obtain FDA approval of any of our therapeutic candidates and begin commercializing those products in the United States, our potential exposure under these laws will increase significantly, and our costs associated with compliance with these laws are likely to increase. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material and adverse effect on our business, financial condition, results of operations and prospects, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, integrity oversight and reporting obligations, or reputational harm.

We depend on our information technology systems, and any failure of these systems, or those of our CROs or other third parties with whom we may work, could harm our business. Security breaches, cyber-attacks, loss of data, and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business, results of operations, financial condition and prospects.

We collect and maintain information in that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we may collect, store, process and transmit large amounts of proprietary, sensitive and confidential information, including intellectual property, business information and personal information. It is critical that we do so in a secure manner to maintain the confidentiality, integrity and availability of such information. We have established physical, electronic and organizational measures to safeguard and secure our systems to prevent a data compromise, and rely on commercially available systems, software, tools, and monitoring to provide security for our information technology systems and the processing, transmission and storage of information. We face a number of risks relative to protecting this critical information, including loss of access risk, inappropriate use or disclosure, inappropriate modification, and the risk of our being unable to adequately monitor, audit, and modify our controls over our critical information. We have also outsourced elements of our information technology infrastructure, and as a result these risks extend to third parties with whom we work, and those third parties may have access to our information.

Despite the implementation of security measures, given the size, complexity, and increasing amounts of proprietary, sensitive, and confidential information maintained by our internal information technology systems and those of our CROs, contract manufacturing organizations (“CMOs”), vendors, contractors, consultants, and other third party partners, such systems are vulnerable to breakdown, service interruptions, system malfunction, accidents by our personnel or third party partners, natural disasters, terrorism, global pandemics, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our personnel or those of our CROs, CMOs, vendors, contractors, consultants, business partners and/or other third party partners, or from cyber-attacks (including through viruses, phishing attacks, spamming, worms, malicious code, malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and the

confidentiality, integrity and availability of information), which may compromise our system infrastructure or data, or that of our third party partners, or lead to data leakage.

The risk of a security breach or disruption or data loss, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of sensitive, proprietary or confidential information.

The COVID-19 pandemic is generally increasing the attack surface available for exploitation, as more companies and individuals work online and work remotely, and as such, the risk of a cybersecurity incident potentially occurring, and our investment in risk mitigations against such an incident, is increasing. For example, there has been an increase in phishing and spam emails as well as social engineering attempts from hackers hoping to use the recent COVID-19 pandemic to their advantage. Additionally, ransomware attacks, including those from organized criminal threat actors, nation-states and nation-state supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions, delays, or outages in our operations, disruption of clinical trials, loss of data (including data related to clinical trials), loss of income, significant extra expenses to restore data or systems, reputational loss and the diversion of funds. To alleviate the financial, operational and reputational impact of a ransomware attack it may be necessary to make extortion payments, but we may be unable to do so if applicable laws prohibit such payments.

We have not always been able in the past and may be unable in the future to anticipate all types of security threats, nor may we be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations or hostile foreign governments or agencies. In addition, individuals have in the past and may continue in the future to actively search for and exploit actual and potential vulnerabilities in our or our partners' information technology and communications. For example, in August 2020 we were subject to a cyber-attack that resulted in unauthorized access to certain company email accounts and shared drives. The intruders used this access to induce a series of fraudulent transfers to outside bank accounts resulting in an aggregate loss of approximately $0.7 million. Although we have subsequently reviewed and enhanced our security and payment systems, there can be no assurance that we will not be the target of a similar or more sophisticated attack in the future, which could materially adversely affect our business, results of operations, financial condition and prospects.

To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or those of our CROs, CMOs, vendors, contractors, consultants, and other third party partners, or inappropriate disclosure of proprietary, sensitive, or confidential information, we could incur liability and reputational damage, our product development programs could be materially disrupted, and our therapeutic candidates could be delayed. In addition, the loss of clinical trial data for our therapeutic candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Any breach, loss or compromise of proprietary, sensitive, or confidential personal information may also subject us to civil fines and penalties under relevant state and federal privacy laws in the United States. For example, the California Consumer Privacy Act of 2018 ("CCPA") imposes a private right of action for security breaches that could lead to some form of remedy including regulatory scrutiny, fines, private right of action settlements, and other consequences. In addition, a breach may require notification to governmental agencies, the media or individuals pursuant to various federal and state privacy and security laws, if applicable, including the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH") and its implementing rules and regulations, as well as regulations promulgated by the Federal Trade Commission and state breach notification laws.

We are required to comply with laws, rules and regulations that require us to maintain the security of personal information. Our agreements with certain customers or business partners may require us to use industry-standard or reasonable measures to safeguard personal information. We also may be subject to laws that require us to use industry-standard or reasonable security measures to safeguard personal information. A security breach could lead to claims by our customers, business partners, or other relevant stakeholders that we have failed to comply with such legal or contractual obligations. In addition, our inability to comply with data privacy obligations in our contracts

with customers or business partners, or our inability to flow down customer obligations to our CROs, CMOs, vendors, contractors, consultants, and other third party partners may cause us to breach our customer or partner contracts. As a result, we could be subject to legal action or our customers or business partners could end their relationships with us. There can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages.

Most jurisdictions have enacted laws requiring companies to notify individuals, regulatory authorities, and others of security breaches involving certain types of data. In addition, our agreements with CROs, CMOs, vendors, contractors, consultants, and other third-party partners may require us to notify them in the event of a security breach. Such mandatory disclosures are costly, could lead to negative publicity, may cause our customers to lose confidence in the effectiveness of our security measures and require us to expend significant capital and other resources to respond to and/or alleviate problems caused by the actual or perceived security breach.

The costs to respond to a security breach and/or to mitigate any security vulnerabilities that may be identified could be significant, our efforts to address these issues may not be successful, and these issues could result in interruptions, delays, negative publicity, loss of customer trust, diminished use of our products as well as other harms to our business and our competitive position. Remediation of any potential security breach may involve significant time, resources, and expenses. Any security breach may result in regulatory inquiries, litigation or other investigations, and can affect our financial and operational condition. Litigation resulting from security breaches may adversely affect our business. Unauthorized access to our systems, networks, or physical facilities could result in litigation with our customers or other relevant stakeholders. These proceedings could force us to spend money in defense or settlement, divert management's time and attention, increase our costs of doing business, or adversely affect our reputation.

We may not have adequate insurance coverage for security breaches, including fines, judgments, settlements, penalties, costs, attorney fees and other impacts that arise out of incidents or breaches. The successful assertion of one or more large claims against us that exceeds available insurance coverage, or results in changes to insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage and coverage for errors and omissions will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim. Our risks are likely to increase as we continue to expand, grow our customer base, and process, store, and transmit increasingly large amounts of data.

We are subject to stringent and changing laws, regulations and standards, and contractual obligations relating to privacy, data protection, and data security. The actual or perceived failure to comply with such obligations could lead to government enforcement actions (which could include civil or criminal penalties), fines and sanctions, private litigation and/or adverse publicity and could negatively affect our operating results and business.

We, and third parties who we work with are or may become subject to numerous domestic and foreign laws, regulations, and standards relating to privacy, data protection, and data security, the scope of which is changing, subject to differing applications and interpretations, and may be inconsistent among countries, or conflict with other rules. We are or may become subject to the terms of contractual obligations related to privacy, data protection, and data security. Our obligations may also change or expand as our business grows. The actual or perceived failure by us or third parties related to us to comply with such obligations could increase our compliance and operational costs, expose us to regulatory scrutiny, actions, fines and penalties, result in reputational harm, lead to a loss of customers, result in litigation and liability, and otherwise cause a material adverse effect on our business, financial condition, and results of operations.

In the United States, numerous federal and state laws and regulations govern the collection, use, disclosure and protection of health-related and other personal information and could apply to our operations or the operations of third partners with whom we work. In addition, we may obtain health information from third parties that are subject to privacy and security requirements under HIPAA, as amended by HITECH.

The state of California recently enacted the CCPA, which creates new individual privacy rights for California consumers and places increased privacy and data security obligations on entities handling personal information of consumers or households. The CCPA went into effect on January 1, 2020 and may impact our business activities

and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal information and protected health information. Additionally, although not effective until January 1, 2023, the California Privacy Rights Act ("CPRA"), which expands upon the CCPA, was passed in the election on November 3, 2020. The CCPA gives (and the CPRA will give) California residents expanded privacy rights, including the right to request correction, access, and deletion of their personal information, the right to opt out of certain personal information sharing, and the right to receive detailed information about how their personal information is processed. The CCPA and CPRA provide for civil penalties and a private right of action for data breaches that is expected to increase data breach litigation. The CCPA and CPRA may increase our compliance costs and potential liability. Further, on March 2, 2021, Virginia enacted the Virginia Consumer Data Protection Act, a comprehensive privacy statute that shares similarities with the CCPA, CPRA, and legislation proposed in other states. Similar laws have been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the United States.

Foreign laws and regulations relating to privacy, data protection, and data security, including the General Data Protection Regulation ("GDPR") may apply to health-related and other personal information obtained outside of the United States. The GDPR imposes strict obligations on businesses, including requiring changes to informed consent practices and more detailed notices for clinical trial subjects and investigators, requiring limitations on data processing, establishing a legal basis for processing personal information, notification of data processing obligations, notification of security breaches to appropriate data protection authorities or data subjects, protecting the security and confidentiality of the personal information, and establishing means for data subjects to exercise rights in relation to their personal information. The GDPR subjects noncompliant companies to fines of up to the greater of 20 million Euros or 4% of their global annual revenue, potential bans on processing of personal information (including clinical trials), and private litigation. To the extent applicable, the GDPR may increase our responsibility and liability in relation to personal information that we process, and we may be required to put in place additional mechanisms and expend additional time and resources to ensure compliance with the EU data protection rules.

Additionally, the UK's decision to leave the EU, often referred to as Brexit, and ongoing developments in the UK have created uncertainty regarding data protection regulation in the UK. Following December 31, 2020, and the expiry of transitional arrangements between the UK and EU, the data protection obligations of the GDPR continue to apply to UK-related processing of personal data in substantially unvaried form under the so-called 'UK GDPR' (i.e., the GDPR as it continues to form part of UK law by virtue of section 3 of the EU (Withdrawal) Act 2018, as amended). However, going forward, there is increasing risk for divergence in application, interpretation and enforcement of the data protection laws as between the UK and the rest of Europe. While the European Commission did adopt on June 28, 2021, an adequacy decision for the UK to allow personal data to flow freely from the EU to the UK, the longer term relationship between the UK and the EEA in relation to certain aspects of data protection law remains uncertain.

In addition, European data protection laws prohibit the transfer of personal information to countries outside of the European Economic Area ("EEA"), UK, and Switzerland, such as the United States, which are not considered by the European Commission to provide an adequate level of data protection. Switzerland has adopted similar restrictions. Although there are legal mechanisms to allow for the transfer of personal information from the EEA, UK, and Switzerland to the United States and other countries, they are or may become subject to legal challenges that, if successful, could invalidate these mechanisms, restrict our ability to process personal information of Europeans outside of Europe and adversely impact our business. For example, in July 2020, the European Court of Justice invalidated the EU-U.S. Privacy Shield in a decision that also cast doubt on the validity of the Standard Contractual Clauses, the primary alternative to Privacy Shield. The decision has led to uncertainty regarding the mechanisms for data transfers from Europe to the United States. We may need to implement additional safeguards to further enhance the security of data transferred out of the Europe, which could increase our compliance costs, expose us to further regulatory scrutiny and liability, and adversely affect our business. For example, on June 4, 2021, the European Commission adopted new Standard Contractual Clauses, which impose on companies additional obligations relating to data transfers, including the obligation to conduct a transfer impact assessment and, depending on a party's role in the transfer, to implement additional security measures and to update internal privacy practices. If we elect to rely on the new Standard Contractual Clauses for data transfers, we may be required to incur significant time and resources to update our contractual arrangements and to comply with new obligations. Additionally, other countries (e.g., Australia and Japan) have adopted certain legal requirements for cross-border transfers of personal information.

These obligations may be interpreted and applied in a manner that is inconsistent from one jurisdiction to another and may conflict with other requirements or our practices.

Some countries also are considering or have passed legislation requiring local storage and processing of data, or similar requirements, which could increase the cost and complexity of our business operations. For example, Brazil recently enacted the General Data Protection Law (Lei Geral de Proteção de Dados Pessoais or LGPD) (Law No. 13,709/2018), which broadly regulates the processing of personal information and imposes compliance obligations and penalties comparable to those of the GDPR. To comply with storage and processing requirements and as supervisory authorities continue to issue further guidance, we may need to implement additional safeguards to further enhance the security of data transferred out of Europe. We could suffer additional costs, complaints, or regulatory investigations or fines, and, if we are otherwise unable to transfer personal information between and among countries and regions in which we operate, it could affect the manner in which we provide our products and services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

We are or may become subject to the terms of external and internal policies, representations, certifications, publications related to privacy, data protection, and data security.

Compliance with domestic and foreign privacy, data protection, and data security laws, regulations, standards, and contractual and other obligations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. The actual or perceived failure to comply with our obligations related to privacy, data protection, and data security could result in government enforcement actions (which could include civil, criminal, and administrative penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business.

If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be affected adversely.

Our research and development involves the use of hazardous chemicals and materials, including radioactive materials. We maintain quantities of various flammable and toxic chemicals in our facilities in South San Francisco, California that are required for our research and development activities. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous chemicals and materials. We believe our procedures for storing, handling and disposing these materials in our facilities comply with the relevant guidelines of South San Francisco, California. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards mandated by applicable regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of animals and biohazardous materials. 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 these materials, this insurance may not provide adequate coverage against potential liabilities. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

Our current operations are concentrated in one location, and we or the third parties upon whom we depend may be adversely affected by a wildfire and earthquake or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our current operations are located in our facilities in South San Francisco, California. Any unplanned event, such as flood, wildfire, explosion, earthquake, extreme weather condition, medical epidemic including the COVID-19 pandemic, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party contract manufacturers, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. For example, our operations are concentrated primarily on the west coast of the United States, and any adverse weather event or natural disaster, such as an earthquake, tsunami or wildfire, could have a material adverse effect on a substantial

portion of our operations. Loss of access to these facilities may result in increased costs, delays in the development of our therapeutic candidates or interruption of our business operations. Extreme weather conditions or other natural disasters could further disrupt our operations and have a material and adverse effect on our business, financial condition, results of operations 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 our research facilities or the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. 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. In addition, the long-term effects of climate change on general economic conditions and the pharmaceutical industry in particular are unclear and may heighten or intensify existing risk of natural disasters. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our third-party contract manufacturers, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption could have a material and adverse effect on our business, financial condition, results of operations and prospects.

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

As of December 31, 2021, we had net operating loss carryforwards for federal and California income tax purposes of $59.0 million and $15.6 million, respectively. The federal net operating losses will not be subject to expiration and the California net operating losses begin to expire in 2038. As of December 31, 2021, we also had available tax credit carryforwards for federal and California income tax purposes of $1.9 million and $1.4 million, respectively. The federal tax credits begin to expire in 2038 and the California tax credits will not be subject to expiration. To the extent that our taxable income exceeds any current year operating losses, we plan to use our carryforwards to offset income that would otherwise be taxable. Under the Tax Cuts and Jobs Act of 2017 (as modified by the Coronavirus Aid Relief and Economic Security Act of 2021), federal net operating losses generated after December 31, 2017 will not be subject to expiration. However, utilization of carryforwards generated in tax years beginning after December 31, 2017 are limited to a maximum of 80% of the taxable income for such year determined without regard to such carryforwards. Also, for state income tax purposes, the extent to which states will conform to the federal laws is uncertain and there may be periods during which the use of NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For example, California imposed limits on the usability of California state NOLs and tax credits in tax years beginning after 2019 and before 2023. In addition, under Section 382 of the Code, changes in our ownership may limit the amount of our net operating loss carryforwards and tax credit carryforwards that could be utilized annually to offset our future taxable income, if any. This limitation would generally apply in the event of a cumulative change in ownership of our company of more than 50% within a three-year period. We have not performed an analysis to determine whether there has been an ownership change pursuant to Section 382. Any such limitation may significantly reduce our ability to utilize our net operating loss carryforwards and tax credit carryforwards before they expire. Various transactions that have occurred since our inception may trigger such an ownership change pursuant to Section 382. Any such limitation, whether as the result of prior offerings of securities, future sales of our common stock by our existing stockholders or additional sales of our common stock by us, could have a material adverse effect on our results of operations in future years.

Risks Related to Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for our therapeutic candidates, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our therapeutics may be adversely affected.

We rely upon a combination of patents, know-how and confidentiality agreements to protect the intellectual property related to our therapeutics and technologies and to prevent third parties from copying and surpassing our achievements, thus eroding our competitive position in our market.

Our success depends in large part on our ability to obtain and maintain patent protection for our therapeutic candidates and their uses, as well as our ability to operate without infringing the proprietary rights of others. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel discoveries and technologies that are important to our business. Our pending and future patent applications may not result in patents being issued or that issued patents will afford sufficient protection of our therapeutic 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 therapeutic candidates.

Obtaining and enforcing patents is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications or maintain and/or enforce patents that may issue based on our patent applications, at a reasonable cost or in a timely manner, including delays as a result of the COVID-19 pandemic impacting our or our licensors' operations. It is also possible that we will fail to identify patentable aspects of our research and development results before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

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

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation, resulting in court decisions, including Supreme Court decisions, which have increased uncertainties as to the ability to enforce patent rights in the future. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we will be successful in protecting our therapeutic candidates by obtaining and defending patents. For example, we may not be aware of all third-party intellectual property rights potentially relating to our therapeutic candidates or their intended uses, and as a result the impact of such third-party intellectual property rights upon the patentability of our own patents and patent applications, as well as the impact of such third-party intellectual property upon our freedom to operate, is highly uncertain. Patent applications in the United States and other jurisdictions are typically not published until 18 months after 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 our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, inventorship, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending patent applications may be challenged in patent offices in the United States and abroad. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. For example, our pending patent applications may be subject to third-party pre-issuance submissions of

prior art to the USPTO or our issued patents may be subject to post-grant review ("PGR") proceedings, oppositions, derivations, reexaminations, or inter partes review ("IPR") proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such challenges may result in loss of exclusivity 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 products, or limit the duration of the patent protection of our technology and products. In addition, given the amount of time required for the development, testing and regulatory review of new therapeutic candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Any failure to obtain or maintain patent protection with respect to our therapeutic candidates or their uses could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. We may also rely on trade secret protection as temporary protection for concepts that may be included in a future patent filing. However, trade secret protection will not protect us from innovations that a competitor develops independently of our proprietary know how. If a competitor independently develops a technology that we protect as a trade secret and files a patent application on that technology, then we may not be able to patent that technology in the future, may require a license from the competitor to use our own know-how, and if the license is not available on commercially-viable terms, then we may not be able to launch our therapeutic. Although we require all of our employees to assign their inventions to us, and 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 confidentiality agreements, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. 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, and this scenario could materially adversely affect our business, financial condition and results of operations.

We cannot ensure that patent rights relating to inventions described and claimed in our pending patent applications will issue or that patents based on our patent applications will not be challenged and rendered invalid and/or unenforceable.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our therapeutic candidates by obtaining and defending patents. We have pending U.S. and foreign patent applications in our portfolio covering our therapeutic programs. We cannot predict:

- if and when patents may issue based on our patent applications;
- the scope of protection of any patent issuing based on our patent applications;
- whether the claims of any patent issuing based on our patent applications will provide protection against competitors;
- whether or not third parties will find ways to invalidate or circumvent our patent rights;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications;
- whether we will need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;
- whether the patent applications that we own will result in issued patents with claims that cover our therapeutic candidates or uses thereof in the United States or in other foreign countries; and

- whether, if the COVID-19 pandemic continues to spread around the globe, we may experience patent office interruption or delays to our ability to timely secure patent coverage to our therapeutic candidates.

We cannot be certain that the claims in our pending patent applications directed to our therapeutic candidates and/or technologies will be considered patentable by the USPTO or by patent offices in foreign countries. There can be no assurance that any such patent applications will issue as granted patents. One aspect of the determination of patentability of our inventions depends on the scope and content of the "prior art," information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim. Even if the patents do issue based on our patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents in our portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our therapeutic candidates is threatened, it could dissuade companies from collaborating with us to develop and threaten our ability to commercialize our therapeutic candidates. In the event of litigation or administrative proceedings, we cannot be certain that the claims in any of our issued patents will be considered valid by courts in the United States or foreign countries.

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

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

Geo-political actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. For example, the United States and foreign government actions related to Russia's invasion of Ukraine may limit or prevent filing, prosecution and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an event were to occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees that have citizenship or nationality in, are registered in, or have predominately primary place of business or profit-making activities in the United States and other countries that Russia has deemed unfriendly without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Various companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights.

Various countries outside the United States 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. As a result, a patent owner may have limited remedies in certain circumstances, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected. 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.

Further, the standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. As such, we do not know the degree of future protection that we will have on our technologies, products and therapeutic candidates. While we will endeavor to try to protect our technologies, products and therapeutic candidates with intellectual property rights such as patents, as appropriate, the process of obtaining patents is time consuming, expensive and unpredictable.

No earlier than October 1, 2022, European applications will soon have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court ("UPC"). This will be a significant change in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation.

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

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

- others may be able to make therapeutic candidates that are similar to ours but that are not covered by the pending patent applications that we own;
- we or our licensors or future collaborators might not have been the first to make the inventions covered by the pending patent application that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that noncompliance with the USPTO and foreign governmental patent agencies requirement for a number of procedural, documentary, fee payment and other provisions during the patent process can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents, if any arise in the future, that we either own or have exclusively licensed may be revoked, modified, or held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- we cannot predict the scope of protection of any patent issuing based on our patent applications, including whether the patent applications that we own or, in the future, in-license will result in issued patents with claims that directed to our therapeutic candidates or uses thereof in the United States or in other foreign countries;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns;

- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing therapeutic candidates;
- the claims of any patent issuing based on our patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties;
- if enforced, a court may not hold that our patents, if they issue in the future, are valid, enforceable and infringed;
- we may need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such intellectual property;
- we may fail to adequately protect and police our trademarks and trade secrets; and
- the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patent applications.

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

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our therapeutics.

As the biopharmaceutical industry expands and more patents are issued, the risk increases that our therapeutic candidates may be subject to claims of infringement of the patent rights of third parties. There can be no assurance that our operations do not, or will not in the future, infringe existing or future third-party patents. Identification of third-party patent rights that may be relevant to our operations is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our therapeutic candidates in any jurisdiction.

Numerous U.S. and foreign patents and pending patent applications exist in our market that are owned by third parties. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our therapeutics. We do not always conduct independent reviews of pending patent applications of and patents issued to third parties. Patent applications in the United States and elsewhere are typically published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain U.S. applications that will not be filed outside the U.S. can remain confidential until patents issue. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived. Furthermore, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our therapeutics or the use of our therapeutics. As such, there may be applications of others now pending or recently revived patents of which we are unaware. These patent applications may later result in issued patents, or the revival of previously abandoned patents, that will prevent, limit or otherwise interfere with our ability to make, use or sell our therapeutics.

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. For example, we may incorrectly determine that our therapeutics are not covered by a third-party patent or may incorrectly predict whether a third-party’s pending application will issue with claims of relevant

scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our therapeutics.

We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, including our research programs, therapeutic candidates, their respective methods of use, manufacture and formulations thereof, and could result in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

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

Because our development programs may in the future require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license, or use these third-party proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our therapeutic candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These 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 successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or therapeutic candidate, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

While we normally seek to obtain the right to control prosecution, maintenance and enforcement of the patents relating to our therapeutic candidates, there may be times when the filing and prosecution activities for patents and patent applications relating to our therapeutic candidates are controlled by our future licensors or collaboration partners. If any of our future licensors or collaboration partners fail to prosecute, maintain and enforce such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patents covering our therapeutic candidates, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize those therapeutic candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensees, our future licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

We may enter into license agreements in the future with others to advance our existing or future research or allow commercialization of our existing or future therapeutic candidates. These licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and therapeutics in the future.

In addition, subject to the terms of any such license agreements, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications covering the technology that we license from third parties. In such an event, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business. If our future licensors fail to prosecute, maintain, enforce, and defend such patents or patent applications, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our future therapeutic candidates that are subject of such licensed rights could be adversely affected.

Our future licensors may rely on third-party consultants or collaborators or on funds from third parties such that our future licensors are not the sole and exclusive owners of the patents we in-license. If other third parties have ownership rights to our future 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.

It is possible that we may be unable to obtain licenses at a reasonable cost or on reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to redesign our technology, therapeutic candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected therapeutic candidates, which could harm our business, financial condition, results of operations, and prospects significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, manufacturing methods, therapeutic candidates, or future methods or products resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

Disputes may arise between us and our 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 on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- our right to transfer or assign the license;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our future licensors and us and our partners; and
- the priority of invention of patented technology.

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

In spite of our best efforts, our future licensors might conclude that we materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize therapeutics and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, therapeutics identical to ours. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

From time to time, we may be required to license technologies relating to our therapeutic research programs from additional third parties to further develop or commercialize our therapeutic candidates. Should we be required to obtain licenses to any third-party technology, including any such patents required to manufacture, use or sell our therapeutic candidates, such licenses may not be available to us on commercially reasonable terms, or at all. The

inability to obtain any third-party license required to develop or commercialize any of our therapeutic candidates could cause us to abandon any related efforts, which could seriously harm our business and operations.

Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our therapeutics or may elect not to continue or renew development or commercialization programs based on trial or test 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, or the ongoing COVID-19 pandemic;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our therapeutic candidates;
- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of our future therapeutic candidates or that results 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 future therapeutic candidates;
- collaborators may own or co-own intellectual property covering our therapeutics that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator’s sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

Our technology licensed from various third parties may be subject to retained rights.

Our future licensors may retain certain rights under the relevant 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 (“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. We sometimes collaborate with academic institutions to accelerate our preclinical research or development. While it is our policy to avoid engaging university partners in projects in which there is a risk that federal funds may be commingled, we cannot be sure that any co-developed intellectual property will be free from

government rights pursuant to the Bayh-Dole Act. 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 are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our therapeutic candidates.

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our therapeutic candidates without infringing the intellectual property and other proprietary rights of third parties. Third parties may allege that we have infringed or misappropriated their intellectual property. Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming and, even if resolved in our favor, is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their 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.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our therapeutic candidates. We cannot be certain that our therapeutic candidates and other proprietary technologies we may develop will not infringe existing or future patents owned by third parties. Third parties may assert infringement claims against us based on existing or future intellectual property rights. In the United States, proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. If we are found to infringe a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing therapeutic candidate or therapeutic. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing therapeutic candidate or therapeutic. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our investigational products or force us to cease some of our business operations, which could materially harm our business.

We may not be aware of patents that have already been issued and that a third party, for example, a competitor in the fields in which we are developing our therapeutic candidates, might assert are infringed by our future therapeutic candidates, including claims to compositions, formulations, methods of manufacture or methods of use or treatment that cover our therapeutic candidates. 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 therapeutic candidates and other proprietary technologies we may develop, could be found to be infringed by our therapeutic candidate. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our therapeutic candidates may infringe. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our therapeutic candidates. The pharmaceutical and biotechnology industries have produced a considerable number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our therapeutic candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may

not be able to do this. Proving invalidity may be difficult. For example, in the United States, proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents, and there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on our business and operations. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

We may choose to challenge the enforceability or validity of claims in a third party's U.S. patent by requesting that the USPTO review the patent claims in an ex-parte re-exam, IPR or PGR proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third party's patent in patent opposition proceedings in the EPO, or other foreign patent office. The costs of these opposition proceedings could be substantial, and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office then we may be exposed to litigation by a third party alleging that the patent may be infringed by our therapeutic candidates or proprietary technologies.

If we are found to infringe a third-party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing therapeutic candidate or product. Alternatively, we may be required to obtain a license from such third-party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing therapeutic candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our therapeutic candidates or force us to cease some of our business operations, and could divert the time and attention of our technical personnel and management, cause development delays, and/or require us to develop non-infringing technology, which may not be possible on a cost-effective basis, any of which could materially harm our business. In the event of a successful claim of infringement against us, we may have to pay substantial monetary damages, including treble damages and attorneys' fees for willful infringement, pay royalties and other fees, redesign our infringing drug or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors or other third parties may infringe our future patents, trademarks or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In patent litigation in the United States, 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, including lack of novelty, obviousness, non-enablement or insufficient written description. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention, or decide that the other party's use of our future patented technology falls under the safe harbor to patent infringement under 35 U.S.C.

§271(e)(1). An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Moreover, we cannot assure you that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may conclude that even if a third-party is infringing any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders, or it may be otherwise impractical or undesirable to enforce our intellectual property against some third parties. Our competitors or other third parties may be able to sustain the costs of complex patent litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs, in-license needed technology or other therapeutic candidates, or enter into development partnerships that would help us bring our therapeutic candidates to market.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

As is common in the pharmaceutical industry, in addition to our employees, we engage the services of consultants to assist us in the development of our therapeutic candidates. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other pharmaceutical companies including our competitors or potential competitors. We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of former employers or competitors. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may become subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor.

While we may litigate to defend ourselves against these claims, even if we are successful, litigation could result in substantial costs and could be a distraction to management. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to our therapeutic candidates, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to

collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

Changes in patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our therapeutic candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs, and may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our future owned and licensed patents. Patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act ("Leahy-Smith Act"), signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. 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 PGR, IPR, and derivation proceedings.

Further, because of a lower evidentiary standard in these USPTO post-grant 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. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

After March 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements 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 after March 2013, but before we file an application covering the same invention, 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 going forward 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 therapeutic candidates and other proprietary technologies we may develop or (ii) invent any of the inventions claimed in our or our licensor's patents or patent applications. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing the claimed invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future 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 pharmaceuticals are particularly uncertain. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents and patents that we might obtain in the future. For example, in

the 2013 case Assoc. for Molecular Pathology v. Myriad Genetics, Inc., the U.S. Supreme Court held that certain claims to DNA molecules are not patentable. We cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents.

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

Periodic maintenance fees, renewal fees, annuities fees and various other governmental fees on patents and/or patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent and/or patent application. The USPTO and various foreign governmental patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse, including due to the effect of the COVID-19 pandemic on us or our patent maintenance vendors, can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our therapeutic candidates, our competitive position would be adversely affected.

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

In addition to seeking patents for some of our technology and therapeutic candidates, we may also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Elements of our therapeutic candidate, including processes for their identification, preparation and manufacture, may involve proprietary know-how, information, or technology that is not covered by patents, and thus for these aspects we may consider trade secrets and know-how to be our primary intellectual property. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Because we expect to rely on third parties in the development and manufacture of our therapeutic candidates, we must, at times, share trade secrets with them. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Trade secrets and know-how can be difficult to protect. We require our employees to enter into written employment agreements containing provisions of confidentiality and obligations to assign to us any inventions generated in the course of their employment. We and any third parties with whom we share facilities enter into written agreements that include confidentiality and intellectual property obligations to protect each party's property, potential trade secrets, proprietary know-how, and information. We further seek to protect our potential trade secrets, proprietary know-how, and information in part, by entering into non-disclosure and confidentiality agreements with parties who are given access to them, such as our corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties. With our consultants, contractors, and outside scientific collaborators, these agreements typically include invention assignment obligations. We cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. We cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. 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. Further, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third-party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third-party, our competitive position would be harmed.

We may become subject to claims challenging the inventorship or ownership 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 therapeutic 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 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 or 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 addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property 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.

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

Patent rights are of limited duration. In the United States, if all maintenance fees are paid timely, the natural expiration of a patent is generally 20 years after its first effective filing date. Given the amount of time required for the development, testing and regulatory review of new therapeutic candidates, patents protecting such candidates might expire before or shortly after such therapeutic candidates are commercialized. Even if patents covering our therapeutic candidates are obtained, once the patent life has expired for a product, we may be open to competition from biosimilar or generic products. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing therapeutic candidates similar or identical to ours. Upon issuance in the United States, the term of a patent can be increased by patent term adjustment, which is based on certain delays caused by the USPTO, but this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. The term of a United States patent may also be shortened if the patent is terminally disclaimed over an earlier-filed patent. A patent term extension (“PTE”) based on regulatory delay may be available in the United States. However, only a single patent can be extended for each marketing approval, and any patent can be extended only once, for a single product. Moreover, the scope of protection during the period of the PTE does not

extend to the full scope of the claim, but instead only to the scope of the product as approved. Laws governing analogous PTEs in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family. Additionally, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. If we are unable to obtain PTE or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our therapeutic will be shortened and our competitors may obtain approval of competing products following our patent expiration and may take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to launch their product earlier than might otherwise be the case, and our revenue could be reduced, possibly materially.

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

Our current or future trademarks or trade names may be challenged, infringed, circumvented or declared generic or descriptive or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest.

During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. 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 to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Although 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.

Moreover, any name we have proposed to use with our therapeutic candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names, it may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Risks Related to Government Regulation

We and/or our collaborators may be unable to obtain, or may be delayed in obtaining, U.S. or foreign regulatory approval and, as a result, unable to commercialize our therapeutic candidates.

Our therapeutic candidates are subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, post-approval monitoring, marketing and distribution of drugs. Rigorous

preclinical testing and clinical trials and an extensive regulatory approval process are required to be completed successfully in the United States and in many foreign jurisdictions before a new drug can be marketed. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. It is possible that none of the therapeutic candidates we may develop, either alone or with our collaborators, will obtain the regulatory approvals necessary for us or our existing or future collaborators to begin selling them.

We have no prior experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the MHRA or the FDA. The time required to obtain MHRA or the FDA and other approvals is unpredictable but typically takes many years following the commencement of clinical trials, depending upon the type, complexity and novelty of the therapeutic candidate. The standards that the MHRA, FDA, EMA and their foreign counterparts use when regulating us require judgment and can change, which makes it difficult to predict with certainty their application. Any analysis we perform of data from preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We or our collaborators may also encounter unexpected delays or increased costs due to new government regulations, for example, from future legislation or administrative action, or from changes in MHRA or the FDA policy during the period of product development, clinical trials and MHRA or the FDA regulatory review. It is impossible to predict whether legislative changes will be enacted, or whether MHRA, FDA, EMA or foreign regulations, guidance or interpretations will be changed, or the impact of such changes, if any.

Given that the therapeutic candidates we are developing, either alone or with our current or future collaborators, represent a new therapeutic approach, the MHRA, FDA, EMA and their foreign counterparts may not have established any definitive policies, practices or guidelines in relation to these therapeutic candidates. Moreover, the MHRA or the FDA may respond to any marketing application that we may submit by defining requirements that we do not anticipate. Such responses could delay clinical development of our therapeutic candidates. In addition, because there are approved treatments for some of the diseases for which we may seek approval, in order to receive regulatory approval, we may need to demonstrate through clinical trials that the therapeutic candidates we develop to treat these diseases, if any, are not only safe and effective, but safer or more effective than existing products. Furthermore, in recent years, there has been increased public and political pressure on the FDA with respect to the approval process for new drugs and FDA standards, especially regarding product safety.

Any delay or failure in obtaining required approvals could have a material and adverse effect on our ability to generate revenue from the particular therapeutic candidate for which we are seeking approval. Furthermore, any regulatory approval to market a product may be subject to limitations on the approved uses for which we may market the product or on the labeling or other restrictions.

We are also subject to or may in the future become subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries and may include all of the risks associated with the FDA approval process described above, as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval. FDA approval does not ensure approval by regulatory authorities outside the United States and vice versa. Any delay or failure to obtain U.S. or foreign regulatory approval for a therapeutic candidate could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Even if we receive regulatory approval for any of our therapeutic candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our therapeutic candidates, if approved, could be subject to labeling and other restrictions and market withdrawal. We may also be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our therapeutics.

Any regulatory approvals that we or our existing or future collaborators obtain for our therapeutic candidates may also be subject to limitations on the approved indicated uses for which a therapeutic may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing and surveillance to monitor the safety and efficacy of the therapeutic candidate.

In addition, if the MHRA, FDA, EMA or a comparable foreign regulatory authority approves any of our therapeutic candidates, the manufacturing processes, labeling, packaging, distribution, post-approval monitoring and adverse event reporting, storage, import, export, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. The FDA has significant post-market authority, including the authority to require labeling changes based on new safety information and to require post-market studies or clinical trials to evaluate safety risks related to the use of a product or to require withdrawal of the product from the market. The FDA also has the authority to require a REMS plan after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug. The manufacturing facilities we use to make a future product, if any, will also be subject to periodic review and inspection by the FDA and other regulatory agencies, including for continued compliance with cGMP requirements. The discovery of any new or previously unknown problems with our third-party manufacturers, manufacturing processes or facilities may result in restrictions on the product, manufacturer or facility, including withdrawal of the product from the market. As we expect to rely on third-party manufacturers, we will not have control over compliance with applicable rules and regulations by such manufacturers. Any product promotion and advertising will also be subject to regulatory requirements and continuing regulatory review. The FDA imposes stringent restrictions on manufacturers' communications regarding use of their products. Although clinicians may prescribe products for off-label uses as the FDA and other regulatory agencies do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, they do restrict promotional communications from companies or their sales force with respect to off-label uses of products. In addition, as we do not intend to conduct head-to-head comparative clinical trials for our therapeutic candidates, we will be unable to make comparative claims regarding any other products in the promotional materials for our therapeutic candidates. If we promote our therapeutic candidates in a manner inconsistent with FDA-approved labeling or otherwise not in compliance with FDA regulations, we may be subject to enforcement action. If we or our existing or future collaborators, manufacturers or service providers fail to comply with applicable continuing regulatory requirements in the United States or foreign jurisdictions in which we seek to market our therapeutics, we or they may be subject to, among other things, fines, warning or untitled letters, holds on clinical trials, delay of approval or refusal by the FDA or similar foreign regulatory bodies to approve pending applications or supplements to approved applications, suspension or withdrawal of regulatory approval, product recalls and seizures, administrative detention of products, refusal to permit the import or export of products, operating restrictions, injunction, civil penalties and criminal prosecution.

Subsequent discovery of previously unknown problems with a product, 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 the product, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning or untitled letters or holds on clinical trials;
- refusal by the MHRA or the FDA to approve pending applications or supplements to approved applications filed by us or our strategic partners;
- suspension or revocation of product license approvals;
- product seizure or detention or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

The FDA policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our therapeutic candidates. For example, in December 2016, the 21st Century Cures Act ("Cures Act"), was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and biologics and to spur innovation. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the UK, United States or abroad. Changes in FDA staffing

could result in delays in the FDA's responsiveness or in its ability to review submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all. Similar consequences would also result in the event of another significant shutdown of the federal government such as the one that occurred from December 22, 2018 through January 25, 2019.

We may face difficulties from healthcare legislative reform measures.

Existing regulatory policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our therapeutic candidates. We 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 and we may not achieve or sustain profitability.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act, or together, the ACA, was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, (i) subjected therapeutic biologics to potential competition by lower-cost biosimilars by creating a licensure framework for follow-on biologic products, (ii) prescribed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs and therapeutic biologics that are inhaled, infused, instilled, implanted or injected, (iii) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, (iv) established annual fees and taxes on manufacturers of certain branded prescription drugs and therapeutic biologics apportioned among these entities according to their market share in certain government healthcare programs, (v) established a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts (now 70%) off negotiated prices of applicable brand drugs and therapeutic biologics to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs and therapeutic biologics to be covered under Medicare Part D, (vi) expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability, (vii) expanded the entities eligible for discounts under the Public Health program, (viii) created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research and (ix) established a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services ("CMS"), to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

There have been executive, legislative and judicial efforts to modify, repeal, or otherwise invalidate all, or certain aspects of, the ACA. By way of example, the Tax Cuts and Jobs Act of 2017 (the "Tax Reform Act"), was enacted, effective January 1, 2019, and included, among other things, a provision repealing the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and closed on August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is uncertain how any such challenges and the healthcare measures of the Biden administration will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted to reduce healthcare expenditures. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which began in 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through December 31, 2021 due to the COVID-19 pandemic, unless additional Congressional action is taken.

Moreover, 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 types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, 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 and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, in July 2021, President Biden issued an executive order pertaining to drug pricing, which expressed support for legislation allowing direct negotiation in Medicare Part D and inflationary rebates, and directed various executive branch agencies to take actions to lower drug prices and promote generic competition. Several pending legislative efforts, including President Biden's larger Build Back Better legislative agenda and draft bill text, incorporate these drug pricing reforms in addition to inflationary rebates on Part B and Part D drugs that would be payable on commercial and governmental program utilization, policies aimed at redesigning the Medicare Part D benefit and adopting drug price transparency measures. Drug manufacturers who are unwilling to negotiate with Medicare would be subject to additional excise taxes. Additionally, the plan would impose tax penalties on drug manufacturers that increase the prices of drug products faster than the rate of inflation. If elements of the recently announced prescription drug pricing plan become law, our pricing strategy and commercial prospects may be adversely affected. It is unclear to what extent new statutory, regulatory, and administrative initiatives will be enacted and implemented and to what extent these or any future legislation or regulations by the Biden administration will have on our business, including our ability to generate revenue and achieve profitability.

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that additional state and federal healthcare reform measures will be adopted in the future, particularly in light of the new presidential administration. Such reform measures may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our therapeutics.

Our operations and relationships with healthcare providers, healthcare organizations, customers and third-party payors will be subject to applicable anti-bribery, anti-kickback, fraud and abuse, transparency and other healthcare and privacy laws and regulations, which could expose us to, among other things, enforcement actions, criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Our future arrangements with healthcare providers, healthcare organizations, third-party payors and customers expose us to broadly applicable anti-bribery, fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute our therapeutic candidates. In addition, we may be subject to patient data privacy and security regulation by the U.S. federal government and the states and the foreign governments in which we conduct our business. Restrictions under applicable federal and state anti-bribery and healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, individuals and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal and state healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal criminal and civil false claims laws, including the federal False Claims Act, which can be enforced through civil whistleblower or qui tam actions against individuals or entities, and the Federal Civil Monetary Penalties Laws, which prohibit, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Moreover, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;
- HIPAA, which imposes criminal and civil liability, prohibits, among other things, knowingly and willfully executing, or attempting to execute a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by HITECH, and their respective implementing regulations, including the Final Omnibus Rule published on January 25, 2013, which impose obligations on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates that perform certain services involving the storage, use or disclosure of individually identifiable health information for or on behalf of a covered entity and their covered subcontractors, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information, and require notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information;
- the federal legislation commonly referred to as the Physician Payments Sunshine Act, enacted as part of the ACA, and its implementing regulations, which requires certain manufacturers of covered drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children’s Health Insurance Program, with certain exceptions, to report annually to CMS information on certain payments and other transfers of value to clinicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the clinicians described above and their immediate family members. Beginning calendar year 2021, manufacturers must collect information regarding payments and other transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists,

and certified nurse-midwives for reporting in 2022. The reported data is made available in searchable form on a public website on an annual basis. Failure to submit required information may result in civil monetary penalties;

- state privacy laws and regulations, such as those of California, Massachusetts and Virginia, that impose restrictive requirements regulating the use and disclosure of personal information, including health information. These laws may differ significantly from one another and often to not apply to health information that is subject to HIPAA. For example, in June 2018, California enacted the CCPA (which went into effect on January 1, 2020) and gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used, and provides for civil penalties for violations, as well as a private right of action for data breaches;
- foreign privacy, data protection, and data security laws and regulations, such as the GDPR, which imposes comprehensive obligations on covered businesses to, among other things, make contractual privacy, data protection and data security commitments, cooperate with European data protection authorities, implement security measures, give data breach notifications, and keep records of personal information processing activities;
- the U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof;
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; and
- certain 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 in addition to requiring drug manufacturers to report information related to payments to clinicians and other healthcare providers or marketing expenditures and drug pricing information, and state and local laws that require the registration of pharmaceutical sales representatives,

If we or our future collaborators, manufacturers or service providers fail to comply with applicable federal, state or foreign laws or regulations, we could be subject to enforcement actions, which could affect our ability to develop, market and sell our therapeutics successfully and could harm our reputation and lead to reduced acceptance of our therapeutics by the market. These enforcement actions include, among others:

- exclusion from participation in government-funded healthcare programs; and
- exclusion from eligibility for the award of government contracts for our therapeutics.

Efforts to ensure that our current and future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any such requirements, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, integrity oversight and reporting obligations, or reputational harm, any of which could adversely affect our financial results. These risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management's attention from the operation of our business, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources.

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

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

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

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

Interim reimbursement levels for new drugs, if applicable, may also be insufficient to cover our costs and may not be made permanent. Reimbursement rates may be based on payments allowed for lower cost drugs that are already reimbursed, may be incorporated into existing payments for other services and may reflect budgetary constraints or imperfections in Medicare data. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. As a result, obtaining coverage and reimbursement approval of a therapeutic from a third-party payor is a time consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost effectiveness data for the use of our therapeutics on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. There is significant uncertainty related to the insurance coverage and reimbursement of newly approved therapeutics. Third-party payors often rely upon 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. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for new drugs that we develop and for which we obtain regulatory approval could have a material and adverse effect on our business, financial condition, results of operations and prospects.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended ("FCPA") the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to or from recipients in the public or private sector. We may engage third parties to sell our therapeutics sell our therapeutics outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

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

In some countries, particularly member states of the European Union the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a therapeutic. 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 reimbursement has been obtained. Reference pricing used by various EU member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. To obtain coverage and reimbursement or pricing approvals in some countries, we or current or future collaborators may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our therapeutic candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of any therapeutic candidate approved for marketing is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business, financial condition, results of operations or prospects could be materially and adversely affected. Brexit could lead to legal uncertainty and potentially divergent national laws and regulations, including those related to the pricing of prescription pharmaceuticals, as the UK determines which EU laws to replicate or replace. If the UK were to significantly alter its regulations affecting the pricing of prescription pharmaceuticals, we could face significant new costs.

Risks Related Our Common Stock

Our quarterly and annual operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expense related to the ongoing development of IL-17 program, our lead therapeutic candidate or future development programs;
- results of preclinical and clinical trials, or the addition or termination of ongoing or future clinical trials or funding support by us, or existing or future collaborators or licensing partners;

- our execution of any additional collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under existing or future arrangements or the termination or modification of any such existing or future arrangements;
- any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- additions and departures of key personnel;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- if any of our therapeutic candidates receives regulatory approval, the terms of such approval and market acceptance and demand for such therapeutic candidates;
- the continuing effect of the COVID-19 pandemic on our business and operations;
- regulatory developments affecting our therapeutic candidates or those of our competitors; and
- changes in general market and economic conditions.

If our quarterly or annual operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly or annual fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

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

The trading price of our common stock is likely to be highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control, including without limitation as a result of the COVID-19 pandemic. As a result of this volatility, investors may not be able to sell their common stock at or above the price initially paid for the stock. The market price for our common stock may be influenced by many factors, including the other risks described in this section of this Quarterly Report on Form 10-Q entitled “Risk Factors” and the following:

- results of preclinical studies and clinical trials of our therapeutic candidates, or those of our competitors or our existing or future collaborators;
- regulatory or legal developments in the United States, the UK and/or other countries, especially changes in laws or regulations applicable to our therapeutic candidates;
- the success of competitive products or technologies;
- introductions and announcements of new therapeutics by us, our future commercialization partners, or our competitors, and the timing of these introductions or announcements;
- actions taken by regulatory agencies with respect to our therapeutics, clinical studies, manufacturing process or sales and marketing terms;
- actual or anticipated variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in-license additional technologies or therapeutic candidates;
- developments concerning any future collaborations, including but not limited to those with development and commercialization partners;
- market conditions in the pharmaceutical and biotechnology sectors;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures or capital commitments;

- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our therapeutic candidates;
- our ability or inability to raise additional capital and the terms on which we raise it;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;
- actual or anticipated changes in earnings estimates, development timelines or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- announcement and expectation of additional financing efforts;
- speculation in the press or investment community;
- share price and fluctuations of trading volume of our common stock;
- sales of our common stock by us, insiders or our stockholders;
- the concentrated ownership of our common stock;
- the impact of inflation, including wage inflation;
- changes in accounting principles;
- actions instituted by activist shareholders or others;
- terrorist acts, acts of war or periods of widespread civil unrest;
- political unrest, changes and uncertainty associated with terrorism, hostilities or natural disasters and other calamities, including global pandemics such as COVID-19 and the ongoing conflict in Ukraine; and
- general economic, industry and market conditions.

In addition, the stock market in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme price and volume fluctuations that have been often unrelated or disproportionate to the operating performance of the issuer. These broad market and industry factors may seriously harm 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 "Risk Factors" section, could have a dramatic and adverse impact on the market price of our common stock.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for biopharmaceutical companies, which have experienced significant stock price volatility in recent years. Additionally, market volatility arising from the COVID-19 pandemic may lead to increased shareholder activism if we experience a market valuation that they believe are not reflective of our stock's intrinsic value. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our board of directors could have an adverse effect on our operating results and financial condition.

A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

As of May 6, 2022, we have a total of 38,229,275 shares of common stock outstanding. Shares of restricted stock will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements and Rules 144 and 701 under the Securities Act of 1933, as amended (the "Securities Act").

We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. However, future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of our options, or the perception that such sales may occur, could adversely affect the market price of our common stock.

We also expect that significant additional capital may be needed in the future to continue our planned operations. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. To the extent that additional capital is raised through the sale and issuance of shares or other securities convertible into shares, our stockholders will be diluted. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

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

As of March 31, 2022, our executive officers, directors, beneficial holders of 5% or more of our capital stock and their respective affiliates beneficially owned shares representing a substantial portion of our capital stock. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could delay or prevent a change of control of our company, even if such a change of control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might affect the prevailing market price of our common stock. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

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 or 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 of 2012 ("JOBS Act"). 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 (i) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended ("Sarbanes-Oxley Act"), (ii) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (iii) exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not approved previously. In addition, as an emerging growth company, we are only required to provide two years of audited financial statements and two years of selected financial data in our periodic quarterly and annual filings.

We could be an "emerging growth company" until December 31, 2026, although circumstances could cause us to lose that status earlier, including if we are deemed to be a "large accelerated filer," which occurs when the market value of our common stock that is held by non-affiliates equals or exceeds $700.0 million as of the prior June 30, or if we have total annual gross revenue of $1.07 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31, or if we issue more than $1.0 billion in non-convertible debt during any three-year period before that time, in which case we would no longer be an "emerging growth company" immediately. 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 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 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 share price may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to take advantage of the benefits of this

extended transition period. Our financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards. Until the date that we are no longer an "emerging growth company" or affirmatively and irrevocably opt out of the exemption provided by Section 7(a)(2)(B) of the Securities Act, upon issuance of a new or revised accounting standard that applies to our financial statements and that has a different effective date for public and private companies, we will disclose the date on which adoption is required for non-emerging growth companies and the date on which we will adopt the recently issued accounting standard.

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

Anti-takeover provisions in our charter documents and under Delaware law could prevent or delay an acquisition of us, which may be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.

Our restated certificate of incorporation and our restated bylaws contain provisions that could delay or prevent a change in control of our company. These provisions could also make it difficult for stockholders to elect directors who are not nominated by current members of our board of directors or take other corporate actions, including effecting changes in our management. These provisions:

- establish a classified board of directors so that not all members of our board are elected at one time;
- permit only the board of directors to establish the number of directors and fill vacancies on the board;
- provide that directors may only be removed "for cause" and only with the approval of two-thirds of our stockholders;
- require super-majority voting to amend some provisions in our restated certificate of incorporation and restated bylaws;
- authorize the issuance of "blank check" preferred stock that our board could use to implement a stockholder rights plan;
- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- prohibit cumulative voting; and
- establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings.

In addition, Section 203 of the Delaware General Corporation Law ("DGCL") may discourage, delay or prevent a change in control of our company. Section 203 imposes certain restrictions on mergers, business combinations and other transactions between us and holders of 15% or more of our common stock.

The exclusive forum provision in our restated certificate of incorporation may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or

employees, or the underwriters of any offering giving rise to such claim, which may discourage lawsuits with respect to such claims.

Our restated certificate of incorporation, to the fullest extent permitted by law, provides that the Court of Chancery of the State of Delaware is the exclusive forum for: any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the DGCL, our restated certificate of incorporation, or our restated bylaws; or any action asserting a claim that is governed by the internal affairs doctrine. This exclusive forum provision does not apply to suits brought to enforce a duty or liability created by the Securities Exchange Act of 1934, as amended ("Exchange Act"). It could apply, however, to a suit that falls within one or more of the categories enumerated in the exclusive forum provision.

This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, or the underwriters of any offering giving rise to such claims, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provisions contained in our restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations and financial condition.

Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all claims brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. Our restated bylaws provide that the federal district courts of the United States of America, to the fullest extent permitted by law, shall be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act ("Federal Forum Provision"), including for all causes of action asserted against any defendant named in such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering. Our decision to adopt a Federal Forum Provision followed a decision by the Supreme Court of the State of Delaware holding that such provisions are facially valid under Delaware law. While federal or state courts may not follow the holding of the Delaware Supreme Court or may determine that the Federal Forum Provision should be enforced in a particular case, application of the Federal Forum Provision means that suits brought by our stockholders to enforce any duty or liability created by the Securities Act must be brought in federal court and cannot be brought in state court, and our stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

Section 27 of the Exchange Act creates exclusive federal jurisdiction over all claims brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. In addition, neither the exclusive forum provision nor the Federal Forum Provision applies to suits brought to enforce any duty or liability created by the Exchange Act. Accordingly, actions by our stockholders to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder must be brought in federal court, and our stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

Any person or entity purchasing or otherwise acquiring or holding any interest in any of our securities shall be deemed to have notice of and consented to our exclusive forum provisions, including the Federal Forum Provision. These provisions may limit a stockholders' ability to bring a claim, and may result in increased costs for a stockholder to bring such a claim, in a judicial forum of their choosing for disputes with us or our directors, officers, or other employees, or the underwriters of any offering giving rise to such claim, which may discourage lawsuits against us and our directors, officers, and other employees.

Because we do not anticipate paying any 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 dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development, operation and expansion of our business and do not anticipate declaring or paying any dividends for the foreseeable future. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

General Risk Factors

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

The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us or our business. We do not have any control over the industry or securities analysts, or the content and opinions included in their reports. In addition, if no or few securities or industry analysts continue or commence coverage of us, the trading price for our common stock could be impacted negatively. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our preclinical studies and clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of such analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause a decline in our stock price or trading volume.

We will continue to incur increased costs as a result of operating as a public company, and our management will continue to be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after we are no longer an "emerging growth company," we will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. In addition, changing laws, regulations, and standards relating to corporate governance and public disclosure, including those related to climate change and other environmental, social and governance focused disclosures, are creating uncertainty for public companies, increasing legal and financial compliance costs, and making some activities more time consuming. Our management and other personnel will continue to devote a substantial amount of time to these compliance initiatives, and we will continue to incur increased legal and financial compliance costs. For example, we expect that maintaining customary public company director and officer liability insurance will require substantial expenditures. The impact of these legal and financial requirements could 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. The increased costs may require us to reduce costs in other areas of our business or increase the prices of our therapeutic candidates, once commercialized. Moreover, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

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

Pursuant to Section 404 of the Sarbanes-Oxley Act, our management will be required to report upon the effectiveness of our internal control over financial reporting beginning with annual report for our fiscal year ending December 31, 2022. When we lose our status as an "emerging growth company" and become an "accelerated filer" or a "large accelerated filer," we will be required to have an audit of the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing, and possible remediation. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. This process will be time-consuming, costly and complicated.

Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations, or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by the Nasdaq Global Market, the SEC, or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

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

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make any related party transaction disclosures. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected. In addition, we do not have a formal risk management program for identifying and addressing risks to our business in other areas.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock may be volatile. The stock market in general, and Nasdaq and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management’s attention from other business concerns, which could seriously harm our business.

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

Unregistered Sales of Equity Securities

None.

Use of Proceeds

On September 17, 2021, we closed our initial public offering, and issued 13,800,000 shares of common stock at a price of $17.00 per share for net proceeds of $214.7 million, after deducting underwriting discounts, commissions, and other expenses of $19.9 million, and including the full exercise of the underwriters' option to purchase additional shares. None of the expenses associated with the IPO were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to their associates. BofA Securities Inc., SVB Leerink LLC and Evercore Group L.L.C. acted as joint bookrunning managers for the offering.

There has been no material change in the planned use of proceeds from our IPO as described in the Annual Report.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

See Exhibit Index.

EXHIBIT INDEX

Exhibit No.	Description	Incorporated by Reference				Filed herewith
		Form	File No.	Exhibit	Filing Date	
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.					X
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.					X
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.					X
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.					X
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document.					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.					X
104	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101).					X

* This certification is not deemed “filed” for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

SIGNATURES

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

DICE Therapeutics, Inc.

Date: May 12, 2022 By: /s/ J. Kevin Judice, Ph.D.

J. Kevin Judice, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Date: May 12, 2022 By: /s/ Scott Robertson

Scott Robertson
Chief Business and Financial Officer
(Principal Accounting and Financial Officer)

Exhibit 31.1

CERTIFICATION OF PERIODIC REPORT UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, J. Kevin Judice, Ph.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of DICE 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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

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

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

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

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

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

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

Date: May 12, 2022

By: /s/ J. Kevin Judice, Ph.D.
J. Kevin Judice, Ph. D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PERIODIC REPORT UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Scott Robertson, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of DICE 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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

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

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

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

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

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

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

Date: May 12, 2022

By: /s/ Scott Robertson
Scott Robertson
Chief Business and Financial Officer
(Principal Accounting and 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

I, J. Kevin Judice, Ph.D., Chief Executive Officer of DICE Therapeutics, Inc. (the "Company"), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) the Quarterly Report on Form 10-Q of the Company for the quarter ended March 31, 2022 (the "Report"), as filed with the Securities and Exchange Commission, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: May 12, 2022

/s/ J. Kevin Judice

J. Kevin Judice, Ph.D.
Chief Executive Officer
(Principal 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

I, Scott Robertson, Chief Business and Financial Officer of DICE Therapeutics, Inc. (the "Company"), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) the Quarterly Report on Form 10-Q of the Company for the quarter ended March 31, 2022 (the "Report"), as filed with the Securities and Exchange Commission, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: May 12, 2022

/s/ Scott Robertson

Scott Robertson
Chief Business and Financial Officer
(Principal Accounting and Financial Officer)