UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2021

OR

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

For the transition period from to

Commission File Number: 001-39941

Sana Biotechnology, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**83-1381173**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

188 East Blaine Street, Suite 400
Seattle, Washington 98102
(Address of principal executive offices)

Registrant's telephone number, including area code: (206) 701-7914

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

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

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

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

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

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

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

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

As of May 4, 2021, the registrant had 187,675,648 shares of common stock, $0.0001 par value per share, outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including those statements highlighted below. In some cases, you can identify these statements by forward-looking words such as “aim,” “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “plan,” “potential,” “predict,” “should,” “would,” or “will,” the negative of these terms, and other comparable terminology. These forward-looking statements, which are subject to risks, include, but are not limited to, statements about:

- our expectations regarding the potential market size and size of the potential patient populations for our product candidates and any future product candidates, if approved for commercial use;
- our clinical and regulatory development plans;
- our expectations with regard to the results of our clinical studies, preclinical studies and research and development programs, including the timing and availability of data from such studies;
- the timing of commencement of future nonclinical studies and clinical trials and research and development programs;
- our ability to acquire, discover, develop and advance product candidates into, and successfully complete, clinical trials;
- our intentions and our ability to establish collaborations and/or partnerships;
- the timing or likelihood of regulatory filings and approvals for our product candidates;
- our commercialization, marketing and manufacturing, including the buildout of our own manufacturing facility, capabilities and expectations;
- impact from future regulatory, judicial, and legislative changes or developments in the United States and foreign countries;
- our intentions with respect to the commercialization of our product candidates;
- the pricing and reimbursement of our product candidates, if approved;
- the potential effects of public health crises, such as the COVID-19 pandemic, on our preclinical and clinical programs and business;
- our expectations regarding the impact of the COVID-19 pandemic on our business;
- the implementation of our business model and strategic plans for our business and product candidates, including additional indications for which we may pursue;
- our ability to effectively manage our growth, including our ability to retain and recruit personnel, and maintain our culture;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates, including the projected terms of patent protection;
- estimates of our expenses, future revenue, capital requirements, our needs for additional financing and our ability to obtain additional capital;
- our expected use of proceeds from our initial public offering and our existing cash, cash equivalents, and marketable securities;
- the performance of our third-party suppliers and manufacturers;
- our future financial performance;
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act; and
- developments and projections relating to our competitors and our industry, including competing products.

We have based these forward-looking statements largely on our current expectations, estimates, forecasts and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. In light of the significant uncertainties in these forward-looking statements, you should not rely upon forward-looking statements as predictions of future events. Although we believe that we have a reasonable basis for each forward-looking statement contained in this report, 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 at all. You should refer to the sections titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. Other

sections of this report may include additional factors that could harm our business and financial performance. New risk factors emerge from time to time, and it is not possible for our management to predict all risk factors 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, or implied by, any forward-looking statements. In light of the significant uncertainties in these forward-looking statements, you should not rely upon forward-looking statements as predictions of future events. Except as required by law, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

Sana Biotechnology, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except per share amounts)

	March 31, 2021 (unaudited)	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 750,687	$ 124,806
Marketable securities	209,550	253,458
Prepaid expenses and other current assets	7,237	6,203
Total current assets	967,474	384,467
Property and equipment, net	50,986	46,775
Operating lease right-of-use assets	61,770	63,168
Restricted cash	2,143	2,143
Long-term marketable securities	21,627	33,731
Intangible asset	59,195	59,195
Goodwill	140,627	140,627
Other non-current assets	644	190
TOTAL ASSETS	$ 1,304,466	$ 730,296
LIABILITIES, CONVERTIBLE PREFERRED STOCK, AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 4,258	$ 2,253
Accrued compensation	10,811	16,020
Accrued expenses and other current liabilities	11,171	9,466
Operating lease liabilities	3,910	3,712
Success payment liabilities	5,000	-
Total current liabilities	35,150	31,451
Operating lease liabilities, net of current portion	66,349	68,197
Contingent consideration	133,294	121,901
Success payment liabilities, net of current portion	187,151	76,494
Other non-current liabilities	539	540
Total liabilities	422,483	298,583
Commitments and contingencies (Note 10)		
Convertible preferred stock, $0.0001 par value; zero and 537,786 shares authorized as of March 31, 2021 and December 31, 2020, respectively; zero and 134,113 shares issued and outstanding as of March 31, 2021 and December 31, 2020, respectively; aggregate liquidation preference of zero and $926,666 as of March 31, 2021 and December 31, 2020, respectively	-	852,897
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; 50,000 and zero shares authorized as of March 31, 2021 and December 31, 2020, respectively; zero shares issued and outstanding as of March 31, 2021 and December 31, 2020, respectively	-	-
Common stock, $0.0001 par value; 750,000 and 707,000 shares authorized as of March 31, 2021 and December 31, 2020, respectively; 178,941 and 16,170 shares issued and outstanding as of March 31, 2021 and December 31, 2020, respectively	18	2
Additional paid-in capital	1,491,958	8,216
Accumulated other comprehensive income	56	30
Accumulated deficit	(610,049)	(429,432)
Total stockholders' equity (deficit)	881,983	(421,184)
TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK, AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 1,304,466	$ 730,296

See accompanying notes.

Sana Biotechnology, Inc.
Condensed Consolidated Statements of Operations
(unaudited)
(in thousands, except per share amounts)

	Three Months Ended March 31,	
	2021	2020
Operating expenses:		
Research and development	$ 168,930	$ 27,320
General and administrative	11,821	5,955
Total operating expenses	180,751	33,275
Loss from operations	(180,751)	(33,275)
Interest income, net	121	395
Other income, net	13	5
Net loss	$ (180,617)	$ (32,875)
Net loss per share, basic and diluted	$ (1.52)	$ (3.04)
Weighted-average shares outstanding, basic and diluted	119,131	10,820

See accompanying notes.

Sana Biotechnology, Inc.
Condensed Consolidated Statements of Comprehensive Loss
(unaudited)
(in thousands)

	Three Months Ended March 31,	
	2021	2020
Net loss	$ (180,617)	$ (32,875)
Other comprehensive income (loss), net of tax:		
Unrealized gain (loss) on marketable securities, net	26	(10)
Total comprehensive loss	$ (180,591)	$ (32,885)

See accompanying notes.

Sana Biotechnology, Inc.
Condensed Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(unaudited)
(in thousands)

	Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Capital	Income	Deficit	(Deficit)
Balance as of December 31, 2020	134,113	$ 852,897	16,170	$ 2	$ 8,216	$ 30	$ (429,432)	$ (421,184)
Conversion of convertible preferred stock into common stock, upon initial public offering	(134,113)	(852,897)	134,113	13	852,884	-	-	852,897
Issuance of common stock in initial public offering, net of $49,220 in offering costs	-	-	27,025	3	626,402	-	-	626,405
Vesting of restricted stock	-	-	1,428	-	-	-	-	
Exercise of stock options	-	-	205	-	298	-	-	298
Stock-based compensation expense	-	-	-	-	4,158	-	-	4,158
Unrealized gain on marketable securities, net	-	-	-	-	-	26	-	26
Net loss	-	-	-	-	-	-	(180,617)	(180,617)
Balance as of March 31, 2021	-	$ -	178,941	$ 18	$ 1,491,958	$ 56	$ (610,049)	$ 881,983

	Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Income	Deficit	Deficit
Balance as of December 31, 2019	106,890	$ 417,359	10,003	$ 1	$ 1,558	$ 26	$ (144,127)	$ (142,542)
Vesting of restricted stock	-	-	1,427	-	-	-	-	-
Exercise of stock options	-	-	2	-	2	-	-	2
Stock-based compensation expense	-	-	-	-	755	-	-	755
Unrealized loss on marketable securities, net	-	-	-	-	-	(10)	-	(10)
Net loss	-	-	-	-	-	-	(32,875)	(32,875)
Balance as of March 31, 2020	106,890	$ 417,359	11,432	$ 1	$ 2,315	$ 16	$ (177,002)	$ (174,670)

See accompanying notes.

Sana Biotechnology, Inc.
Condensed Consolidated Statements of Cash Flows
(unaudited)
(in thousands)

	Three Months Ended March 31,	
	2021	2020
OPERATING ACTIVITIES:		
Net loss	$ (180,617)	$ (32,875)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	2,247	1,265
Stock-based compensation expense	4,158	755
Change in fair value of contingent consideration	11,393	362
Change in fair value of success payment liabilities	115,657	552
Non-cash expense in connection with license agreement	-	373
Non-cash expense for operating lease right-of-use assets	1,398	784
Other non-cash items, net	(1,013)	350
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(1,614)	(501)
Accounts payable	1,599	2,370
Accrued expenses and other liabilities	(3,121)	(2,982)
Net cash used in operating activities	(49,913)	(29,547)
INVESTING ACTIVITIES:		
Purchases of marketable securities	(44,811)	-
Proceeds from sales and maturities of marketable securities	100,342	44,781
Purchases of property and equipment	(6,440)	(5,600)
Net cash provided by investing activities	49,091	39,181
FINANCING ACTIVITIES:		
Proceeds from initial public offering of common stock, net of offering costs	626,405	-
Proceeds from exercise of stock options	298	2
Net cash provided by financing activities	626,703	2
Net increase in cash, cash equivalents, and restricted cash	625,881	9,636
Cash, cash equivalents, and restricted cash at beginning of period	126,949	81,807
Cash, cash equivalents, and restricted cash at end of period	$ 752,830	$ 91,443
SUPPLEMENTAL CASH FLOW DISCLOSURES:		
Tenant improvement allowance included in operating lease liabilities	$ 8,515	$ 3,837
Purchases of property and equipment included in accounts payable and accrued liabilities	$ 3,157	$ 644
Right-of-use assets obtained in exchange for operating lease liabilities	$ -	$ 14,271

See accompanying notes.

1. Organization

Sana Biotechnology, Inc. (the Company or Sana) was incorporated in Delaware on July 13, 2018 (inception) as FD Therapeutics, Inc., and changed its name to Sana Biotechnology, Inc. on September 17, 2018. Sana is a biotechnology company, focusing on utilizing engineered cells as medicines. The Company's operations to date have included identifying and developing potential product candidates, executing preclinical studies, acquiring technology, organizing and staffing the Company, business planning, establishing the Company's intellectual property portfolio, raising capital, and providing general and administrative support for these operations.

Reverse stock split

In January 2021, the Company's board of directors approved an amendment to the Company's amended and restated certificate of incorporation to effect a 1-for-4 reverse stock split of shares of the Company's common and convertible preferred stock, which was effected on January 27, 2021. The par value per share and authorized shares of common and convertible preferred stock were not adjusted as a result of the reverse stock split. All share and per share information included in the accompanying condensed consolidated financial statements have been adjusted to reflect the reverse stock split.

Initial public offering

In February 2021, the Company successfully completed its initial public offering (IPO) of its common stock. In connection with its IPO, the Company issued 27.0 million shares of its common stock, including 3.5 million shares pursuant to the full exercise of the underwriters' option to purchase additional shares, at a price of $25.00 per share, and received $626.4 million in net proceeds, after deducting underwriting discounts and commissions of $45.2 million and offering expenses of $4.0 million. At the closing of the IPO, 134.1 million shares of convertible preferred stock then outstanding were automatically converted into shares of common stock. The related carrying value of the converted preferred stock of $852.9 million was reclassified to common stock and additional paid in-capital.

Need for additional capital

The Company is subject to a number of risks and uncertainties similar to other biotechnology companies in the development stage including, but not limited to, the need to obtain adequate additional funding, possible failure of preclinical testing or clinical trials, the need to obtain marketing approval for its product candidates, competitors developing new technological innovations, the need to successfully commercialize and gain market acceptance of the Company's products, protect the Company's intellectual property and proprietary technology, and the need to attract and retain key scientific and management personnel. If the Company does not successfully commercialize or partner any of its product candidates, it will be unable to generate product revenue or achieve profitability. Until such time as the Company can generate significant revenue from product sales, if ever, it expects to finance its operations from the sale of additional equity or debt financings, or other capital which come in the form of strategic collaborations, licensing, or other arrangements. In the event that additional financing is required, the Company may not be able to raise it on terms acceptable to it, or at all.

The Company has incurred operating losses each year since inception and expects such losses to continue for the foreseeable future. As of March 31, 2021, the Company had cash, cash equivalents, and marketable securities of $981.9 million, and an accumulated deficit of $610.0 million, which includes non-cash charges of $189.7 million and $82.0 million related to the revaluation of the success payment liabilities and contingent consideration, respectively.

2. Summary of significant accounting policies

The accompanying condensed consolidated financial statements and related financial information should be read in conjunction with the audited consolidated financial statements and the related notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2020 filed with the SEC on March 24, 2021 (2020 Form 10-K). The significant accounting policies used in preparation of these condensed consolidated financial statements as of March 31, 2021 and for the three months ended March 31, 2021 and 2020 are consistent with those discussed in Note 2 in the 2020 Form 10-K.

Basis of presentation

The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. The Company's condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States (GAAP).

Use of estimates

The preparation of the financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. The Company evaluates its estimates and 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. The most significant estimates in the Company's condensed consolidated financial statements relate to success payment liabilities, contingent consideration, business combinations, accrued expenses, and the valuation of stock options.

Recent accounting pronouncements

Recently adopted

Accounting Standards Updates (ASU) No. 2016-13, Financial Instruments—Credit Losses (Topic 362): Measurement of Credit Losses on Financial Statements, ASU No. 2019-05 Financial Instruments—Credit Losses (Topic 326): Targeted Transition Relief, ASU No. 2019-11, Codification Improvements to Topic 326, Financial Instruments—Credit Losses

In June 2016, the Financial Accounting Standards Board (FASB) issued ASU 2016-13, Financial Instruments—Credit Losses (Topic 362): Measurement of Credit Losses on Financial Statements (ASU 2016-13). The new standard requires that expected credit losses relating to financial assets measured on an amortized cost basis and available-for-sale debt securities be recorded through an allowance for credit losses. It also limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which the carrying value exceeds fair value and also requires the reversal of previously recognized credit losses if fair value increases. The targeted transition relief standard allows companies an option to irrevocably elect the fair value option of ASC 825-10, Financial Instruments-Overall, applied on an instrument-by-instrument basis for eligible instruments. The Company adopted ASU 2016-13 effective January 1, 2021. The adoption of the guidance did not have a material impact on the condensed consolidated financial statements and related disclosures, and there was no allowance for losses on available-for-sale debt securities attributable to credit risk for the three months ended March 31, 2021.

Not yet adopted

ASU No. 2017-04, Intangibles—Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment

In January 2017, the FASB issued ASU 2017-04, Intangibles—Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment (ASU 2017-04). To address concerns over the cost and complexity of the two-step goodwill impairment test, the amendments in this ASU remove the second step of the test. An entity will instead apply a one-step quantitative test and record the amount of goodwill impairment as the excess of a reporting unit's carrying amount over its fair value, not to exceed the total amount of goodwill allocated to the reporting unit. The new guidance does not amend the optional qualitative assessment of goodwill impairment. The new standard will be effective beginning January 1, 2023. The adoption of ASU 2017-04 is not expected to have a material impact on the Company's consolidated financial statements.

3. Acquisitions

Oscine Corp.

In September 2020, the Company entered into a stock purchase agreement to acquire 100% of the outstanding equity in Oscine for a purchase price of $8.5 million, of which $7.6 million was an upfront cash payment, and $0.9 million was set aside to satisfy certain general representations and warranties as set forth in the stock purchase agreement (Oscine Holdback Amount).

The primary asset acquired in the acquisition was IPR&D technology related to Oscine's glial progenitor *ex vivo* cell engineering programs focused on brain disorders. The Company evaluated the acquisition and determined the screen test, as permitted under ASC 805, *Business Combinations*, was met as the $8.5 million purchase price represented consideration for a single identifiable asset related to the technology. The Company concluded the asset acquired did not meet the definition of a business, and the asset had no alternative future use. The transaction was accounted for as an asset acquisition and the purchase price of $8.5 million was recorded in research and development expense for the three months ended September 30, 2020.

The Oscine Holdback Amount will be held for 15 months, until December 2021, at which time the remainder of the balance, after payment of any claims, will be released. In addition, the Company is required to make up to an aggregate of $225.8 million in future milestone payments upon the achievement of certain development and commercial milestones.

Cobalt Biomedicine, Inc.

In February 2019, the Company acquired 100% of the outstanding equity in Cobalt, a privately-held early-stage biotechnology company developing a platform technology using its fusogen technology to specifically and consistently deliver various biological payloads to cells.

Pursuant to the terms and conditions in the Cobalt acquisition agreement, the Company agreed to pay contingent consideration of up to an aggregate of $500.0 million upon the achievement of certain pre-specified development milestones (Cobalt Contingent Consideration), and a Cobalt Success Payment of up to $500.0 million, payable in cash or stock, at the Company's discretion. The Cobalt Success Payment is payable if, at pre-determined valuation measurement dates, which are an IPO and periodically thereafter, the Company's market capitalization equals or exceeds $8.1 billion, and the Company has an active program based on the fusogen technology in a clinical trial pursuant to an investigational new drug application (IND), or has filed for, or received approval for, a biologics license application (BLA) or new drug application (NDA). The Cobalt Success Payment can be achieved over a maximum of 20 years but could be shorter upon the occurrence of certain events. The IPO in February 2021 did not trigger a success payment to Cobalt.

In addition to an IPO, a valuation measurement date is triggered upon a change of control when at least one company product utilizing technology acquired from Cobalt is the subject of an active research program. If there is a change of control and Company's market capitalization falls below certain thresholds on the change of control date, the amount of the potential Cobalt Success Payment will decrease, and the amount of potential Cobalt Contingent Consideration will increase.

The following table sets forth the different market capitalizations and resulting potential Cobalt Success Payment and additional potential Cobalt Contingent Consideration if there is a change of control subsequent to the IPO:

Sana market capitalization upon a change of control and resulting impact to Cobalt Success Payment and additional potential Cobalt Contingent Consideration	Cobalt Success Payment	Additional potential Cobalt Contingent Consideration
	(in millions)	
Equal to or exceeds $8.1 billion	$ 500	$ -
Equal to or exceeds $7.4 billion, but less than $8.1 billion	150	350
Equal to or exceeds $6.8 billion, but less than $7.4 billion	100	400
Less than $6.8 billion	-	500

The Cobalt Success Payment and Cobalt Contingent Consideration liabilities are carried at fair value with changes in fair value recognized in research and development expense. As of March 31, 2021 and December 31, 2020, the estimated fair value of the Cobalt Success Payment liability was $156.5 million and $64.7 million, respectively, and the estimated fair value of the Cobalt Contingent Consideration was $133.3 million and $121.9 million, respectively. For the three months ended March 31, 2021 and 2020, the Company recognized $91.8 million and $0.3 million in research and development expense in connection with the change in fair value of the Cobalt Success Payment, respectively, and $11.4 million and $0.4 million in research and development expense in connection with the change in fair value of the Cobalt Contingent Consideration, respectively.

4. Intangible asset and goodwill

As of March 31, 2021, the Company had an intangible asset of $59.2 million, which consists of in-process research and development (IPR&D) acquired in 2019 from the Cobalt acquisition. The IPR&D is classified as indefinite-lived until the successful completion of the associated research and development technology, at which point it becomes a finite-lived asset that will be amortized over its estimated useful life. As of March 31, 2021, there was no amortization of the intangible asset. As of March 31, 2021, the Company had goodwill of $140.6 million. The goodwill represents the excess of the purchase price over the estimated fair value of the net assets acquired from the Cobalt acquisition in 2019. There were no impairments of the intangible asset or goodwill since the acquisition.

5. License and collaboration agreements

President and Fellows of Harvard College

In March 2019, the Company entered into an exclusive license agreement with the President and Fellows of Harvard College (Harvard) to access certain intellectual property for the development of hypo-immune cells.

Under the terms of the agreement, the Company may be required to make Harvard Success Payments up to an aggregate of $175.0 million, payable in cash, based on increases in the fair value of the Company's common stock. The potential success payments are based on multiples of increased value ranging from 5x to 40x, based on a comparison of the fair market value of the Company's common stock relative to the original issuance price of $4.00 per share at pre-determined valuation measurement dates which include: the one year anniversary of the IPO and periodically thereafter, a merger, an asset sale, the sale of the majority of the shares held by the Company's Series A convertible preferred stockholders, and the last day of the term of the success payments. The first Harvard valuation measurement date is expected to occur in February 2022, one year from the IPO. The aggregate amount of the Harvard Success Payments does not exceed an aggregate of $175.0 million, which would only occur upon a 40x increase in value. If a higher success payment tier is first met at the same time a lower tier is first met, both tiers will be owed. Any previous success payments made to Harvard are credited against the success payment owed as of any valuation measurement date so that Harvard does not receive multiple success payments in connection with the same threshold. The Harvard Success Payments can be achieved over a maximum of 12 years from the effective date of the agreement. The following table summarizes the potential success payments and common stock price required for payment:

Multiple of Equity Value at Issuance	**5x**	**10x**	**20x**	**30x**	**40x**
Per share common stock price required for payment	$ 20.00	$ 40.00	$ 80.00	$ 120.00	$ 160.00
Success payment(s) (in millions)	$ 5.0	$ 15.0	$ 30.0	$ 50.0	$ 75.0

As of March 31, 2021 and December 31, 2020, the estimated fair value of the Harvard Success Payment liability was $35.7 million and $11.8 million, respectively. As of March 31, 2021 and December 31, 2020, $5.0 million and zero was recorded in short-term liabilities, and $30.7 million and $11.8 million were recorded in long-term liabilities in the condensed consolidated balance sheet, respectively. For the three months ended March 31, 2021 and 2020, the Company recognized $23.9 million and $0.2 million, respectively, in research and development expense of in connection with the change in the estimated fair value of the Harvard Success Payment liability.

In connection with this agreement, the Company also paid Harvard a license payment of $6.0 million in June 2020 that was contingent upon the closing of the Company's Series B convertible preferred stock financing.

6. Restricted cash

As of March 31, 2021 and December 31, 2020, the Company maintained standby letters of credit of $2.1 million, which are collateralized with a bank account at a financial institution in accordance with the lease agreements.

7. Fair value measurements

The following tables summarize the Company's financial assets and liabilities measured at fair value on a recurring basis based on the three-tier fair value hierarchy:

		March 31, 2021			
	Valuation Hierarchy	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Estimated Fair Value
		(in thousands)			
Financial assets:					
Cash equivalents:					
Money market funds	Level 1	$ 708,413	$ -	$ -	$ 708,413
U.S. government and agency securities	Level 2	2,400	-	-	2,400
Corporate debt securities	Level 2	552	-	-	552
Total cash equivalents		711,365	-	-	711,365
Short-term marketable securities:					
U.S. government and agency securities	Level 2	193,058	56	(1)	193,113
Corporate debt securities	Level 2	16,444	-	(7)	16,437
Total short-term marketable securities		209,502	56	(8)	209,550
Long-term marketable securities:					
U.S. government and agency securities	Level 2	17,437	7	-	17,444
Corporate debt securities	Level 2	4,182	1	-	4,183
Total long-term marketable securities		21,619	8	-	21,627
Total financial assets		$ 942,486	$ 64	$ (8)	$ 942,542
Financial liabilities:					
Short-term financial liabilities:					
Success payment liabilities	Level 3	$ 5,000	$ -	$ -	$ 5,000
Long-term financial liabilities:					
Contingent consideration	Level 3	133,294	-	-	$ 133,294
Success payment liabilities	Level 3	187,151	-	-	187,151
Total financial liabilities		$ 325,445	$ -	$ -	$ 325,445

	Valuation Hierarchy	December 31, 2020			
		Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Estimated Fair Value
		(in thousands)			
Financial assets:					
Cash equivalents:					
Money market funds	Level 1	$ 48,359	$ -	$ -	$ 48,359
U.S. government and agency securities	Level 2	40,727	1	(1)	40,727
Corporate debt securities	Level 2	1,138	-	-	1,138
Total cash equivalents		90,224	1	(1)	90,224
Short-term marketable securities:					
U.S. government and agency securities	Level 2	244,637	30	(5)	244,662
Corporate debt securities	Level 2	8,798	-	(2)	8,796
Total short-term marketable securities		253,435	30	(7)	253,458
Long-term marketable securities:					
U.S. government and agency securities	Level 2	33,724	7	-	33,731
Total long-term marketable securities		33,724	7	-	33,731
Total financial assets		$ 377,383	$ 38	$ (8)	$ 377,413
Financial liabilities:					
Long-term financial liabilities:					
Contingent consideration	Level 3	$ 121,901	$ -	$ -	$ 121,901
Success payment liabilities	Level 3	76,494	-	-	76,494
Total financial liabilities		$ 198,395	$ -	$ -	$ 198,395

The Company measures the fair value of money market funds based on quoted prices in active markets for identical assets or liabilities. The Level 2 marketable securities include U.S. government, agency securities, and corporate debt securities and are valued based on either recent trades of securities in inactive markets or quoted market prices of similar instruments and other significant inputs derived from or corroborated by observable market data.

Securities in an unrealized loss position have been in an unrealized loss position for less than one year. The Company determined that there was no material change in the credit risk of the above investments during the three months ended March 31, 2021. As such, an allowance for credit losses would not be recognized. As of March 31, 2021, the Company does not intend to sell such securities, and it is not more-likely-than-not that the Company will be required to sell the securities prior to the recovery of the amortized cost basis.

As of March 31, 2021, all marketable securities had an effective maturity date of two years or less. Investments in securities with maturities of less than one year, or those for which management intends to use to fund current operations, are included in current assets and classified as available-for-sale. As of March 31, 2021, the balance in accumulated other comprehensive income included the net unrealized gains related to the Company's available-for-sale debt securities. There were no material realized gains or losses recognized on the sale or maturity of available-for-sale securities during the three months ended March 31, 2021 or 2020.

The following table sets forth a summary of the changes in the fair value of the Company's Level 3 financial liabilities:

	Contingent Consideration	Cobalt Success Payment Liability	Harvard Success Payment Liability
		(in thousands)	
Balance as of December 31, 2020	$ 121,901	64,694	$ 11,800
Changes in fair value	11,393	91,757	23,900
Balance as of March 31, 2021	$ 133,294	$ 156,451	$ 35,700

Contingent consideration

The Company utilizes significant estimates and assumptions it believes would be made by a market participant in determining the estimated fair value of the Cobalt Contingent Consideration at each balance sheet date. The fair value of the Cobalt Contingent

Consideration was determined by calculating the probability-weighted estimated value of the pre-specified development milestone payments based on the assessment of the likelihood and estimated timing that the milestones would be achieved, and the applicable discount rates. The discount rate captures the credit risk associated with the payment of the contingent consideration when earned and due. The Company assesses these estimates on an on-going basis as additional data impacting the assumptions are obtained.

The fair value of the Cobalt Contingent Consideration was calculated using the following unobservable inputs:

	March 31, 2021		December 31, 2020	
Unobservable Input	Range	Weighted-Average	Range	Weighted-Average
Discount rates	8.3% - 9.7%	8.8%	10.5% - 10.8%	10.6%
Probability of milestone achievement	5.0% - 65.0%	27.9%	2.5% - 65.0%	27.6%

The weighted-average unobservable inputs were calculated based on the relative value of the pre-specified development milestones. The estimated fair value of the Cobalt Contingent Consideration may change significantly as development progresses and additional data are obtained, impacting the assumptions regarding probabilities of successful achievement of the milestones used to estimate the fair value of the liability and the timing in which they are expected to be achieved. In evaluating the fair value assumptions, judgment is required to interpret the market data used to develop the estimates. The estimates of fair value may not be indicative of the amounts that could be realized in a current market exchange. Accordingly, the use of different market assumptions, inputs, and/or different valuation techniques could result in materially different fair value estimates.

Success payments

The Company utilizes significant estimates and assumptions in determining the estimated fair value of the success payment liabilities, and the associated expense or gain at each balance sheet date. The estimated fair value of the Cobalt and Harvard success payment liabilities was determined using a Monte Carlo simulation methodology which models the estimated fair value of the liability based on several key assumptions including: the expected volatility, remaining term, risk-free interest rate, estimated number and timing of valuation measurement dates on the basis of which payment may be triggered, and for the Cobalt Success Payment, the Company's market capitalization, and for the Harvard Success Payments, the per share fair value of the Company's common stock.

The fair values of the Cobalt and Harvard success payment liabilities were calculated using the following unobservable inputs:

	March 31, 2021		December 31, 2020	
Unobservable Input	Cobalt	Harvard	Cobalt	Harvard
Expected stock price volatility	70.0%	70.0%	70.0%	70.0%
Expected term (years)	17.9	10.0	18.1	10.2

8. Property and equipment, net

Property and equipment, net consists of the following:

	March 31, 2021	December 31, 2020
	(in thousands)	
Laboratory equipment	$ 31,921	$ 26,958
Leasehold improvements	23,788	15,598
Construction in progress	4,367	11,180
Computer equipment, software and other	894	776
Total property and equipment, at cost	60,970	54,512
Less: Accumulated depreciation	(9,984)	(7,737)
Property and equipment, net	$ 50,986	$ 46,775

Depreciation expense was $2.2 million and $1.3 million for the three months ended March 31, 2021 and 2020, respectively.

9. Accrued liabilities

Accrued compensation and accrued expenses and other current liabilities consist of the following:

	March 31, 2021	December 31, 2020
	(in thousands)	
Accrued compensation:		
Accrued paid time off	$ 4,561	$ 2,441
Accrued bonuses	3,194	11,582
Other accrued compensation	3,056	1,997
Total accrued compensation	$ 10,811	$ 16,020
Accrued expenses and other current liabilities:		
Accrued research and development	$ 3,121	$ 1,197
Accrued property and equipment	2,594	2,892
Accrued professional fees	2,051	1,717
Other	3,405	3,660
Total accrued expenses and other current liabilities	$ 11,171	$ 9,466

10. Commitments and contingencies

Lease commitments

The Company's lease portfolio is primarily comprised of operating leases for office, laboratory, and non-GMP pilot plant manufacturing space located in Seattle, WA, Cambridge, MA, and South San Francisco, CA. Operating leases have contractual periods expiring between April 2024 and April 2030. These leases contain various rent abatement periods, after which they require monthly lease payments that may be subject to annual increases throughout the lease term. The Seattle and South San Francisco lease agreements provide the Company with the option to renew for an additional period of five years. The Company is not reasonably certain it will renew these leases, and therefore the renewal options are not considered in the remaining lease term. Certain leases provide the Company the right to make tenant improvements, including the addition of laboratory space, and include a lease incentive allowance.

The following table contains additional information related to our operating leases:

Location	Approximate Square Footage	Commencement Dates	Expiration Dates
Seattle, WA	48,086	March 2019 to September 2020	December 2026 to April 2028
Cambridge, MA	56,859	March 2019 to May 2020	November 2025 to February 2028
South San Francisco, CA	66,075	December 2019 to October 2020	April 2024 to April 2030

Throughout the term of the lease agreements, the Company is responsible for paying certain operating costs, in addition to rent, such as common area maintenance, taxes, utilities, and insurance. These additional charges are considered variable lease costs and are recognized in the period in which the costs are incurred.

The following table summarizes the Company's lease costs:

	Three Months Ended March 31,	
	2021	2020
	(in thousands)	
Operating lease cost	$ 2,898	$ 2,444
Shot-term lease cost	512	470
Variable lease cost	1,087	621
Total lease cost	$ 4,497	$ 3,535

As of March 31, 2021, the weighted-average remaining lease term was 7.3 years and the weighted-average incremental borrowing rate was 10.72%.

The following table reconciles the Company's undiscounted operating lease cash flows by fiscal year, to the present value of the operating lease liabilities as of March 31, 2021 (in thousands):

2021 (remaining 9 months)	$	10,300
2022		15,535
2023		15,989
2024		15,663
2025		15,621
2026 and thereafter		42,616
Total undiscounted lease payments		115,724
Less: imputed interest		(36,950)
Less: tenant improvement allowances		(8,515)
Present value of operating lease liabilities	$	70,259

11. Convertible preferred stock

In 2018, the Company issued 11.5 million shares of its Series A-1 convertible preferred stock at $4.00 per share, for gross proceeds of $45.9 million. In 2019, the Company issued 56.0 million shares of its Series A-2 convertible preferred stock at $4.00 per share, for gross proceeds of $224.0 million. In 2020, the Company issued 27.2 million shares of Series B convertible preferred stock at $16.00 per share, for gross proceeds of $435.6 million. Immediately prior to the closing of the Company's IPO in February 2021, all outstanding shares of convertible preferred stock converted into 134.1 million shares of common stock. There were no shares of convertible preferred stock outstanding as of March 31, 2021.

12. Common stock

The Company amended and restated its certificate of incorporation, effective February 2021, increasing the number of shares of all classes of stock the Company has authority to issue to 800.0 million shares, of which 750.0 million shares are common stock, and 50.0 million shares are preferred stock.

As of March 31, 2021, there were 178.9 million shares of the Company's common stock outstanding, excluding 8.6 million shares of restricted common stock outstanding that are subject to vesting requirements.

13. Stock-based compensation

2021 Incentive Award Plan

In February 2021, the Company adopted the 2021 Incentive Award Plan, which became effective on the completion of the Company's IPO. The 2021 Incentive Award Plan provides for a variety of stock-based compensation awards, including stock options, restricted stock awards (RSAs), and restricted stock units (RSUs). In conjunction with adopting the 2021 Incentive Award Plan, the Company discontinued the 2018 Equity Plan and the restricted stock unit plan with respect to new equity awards. The number of shares of the Company's common stock reserved for issuance is subject to automatically increase by 5% of all shares outstanding at the beginning of each calendar year.

2021 Employee Stock Purchase Plan

In February 2021, the Company adopted the 2021 Employee Stock Purchase Plan (2021 ESPP), which became effective on the completion of the Company's IPO. The 2021 ESPP allows eligible employees to purchase shares of the Company's common stock at a discount through payroll deductions of up to 15% of their earnings, subject to plan limitations. Unless otherwise determined by the Company's board of directors, employees are able to purchase shares at 85% of the lower of the fair market value of the Company's common stock on the first date of an offering or on the purchase date. The number of shares of the Company's common stock reserved for issuance under the 2021 ESPP is subject to automatically increase by 1% of all shares outstanding at the beginning of each calendar year. The Company may specify offerings with durations of not more than 27 months and may specify shorter purchase periods within each offering.

2018 Equity Incentive Plan

In October 2018, the Company adopted the 2018 Equity Incentive Plan (2018 Plan) under which it may grant incentive stock options, non-statutory stock options, RSAs, RSUs, and other stock-based awards to any person, including officers, directors, and

consultants. Terms of stock agreements, including vesting requirements, are determined by the Company's board of directors, or by a committee appointed by the board of directors, subject to the provisions of the 2018 Plan.

Stock-based compensation expense

Stock-based compensation expense is recognized in the condensed consolidated statements of operations as follows:

	Three Months Ended March 31,	
	2021	2020
	(in thousands)	
Research and development	$ 2,668	$ 648
General and administrative	1,490	107
Total stock-based compensation expense	$ 4,158	$ 755

Unrecognized stock-based compensation costs related to unvested awards and the weighted-average period over which the costs are expected to be recognized as of March 31, 2021 are as follows:

	Stock Options	RSAs	RSUs
Unrecognized stock-based compensation expense (in thousands)	$ 49,600	$ 2,875	$ 214
Weighted-average period costs expected to be recognized (years)	3.3	1.6	1.9

Stock options

A summary of the Company's stock option activity is as follows:

	Stock Options (in thousands)	Weighted-Average Exercise Price per Share	Weighted-Average Remaining Contractual Life (years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2020	15,677	$ 4.52		
Granted	526	27.14		
Exercised	(205)	1.35		
Forfeited/Cancelled	(217)	3.35		
Outstanding as of March 31, 2021	15,781	$ 5.33	9.2	$ 444,040
Exercisable as of March 31, 2021	2,324	$ 1.46	8.5	$ 74,383

The fair value of stock options granted to employees, directors, and consultants was estimated on the date of grant using the Black-Scholes option pricing model using the following assumptions:

	Three Months Ended March 31,	
Assumptions	2021	2020
Risk free interest rate	0.64% - 1.11%	0.48%-1.51%
Expected volatility	70%	70%
Expected term (years)	5.50 - 6.25	6.25-6.25
Expected dividend	0%	0%

The following table summarizes additional information related to stock option activity:

	Three Months Ended March 31,	
	2021	2020
Weighted average grant date fair value per share for options granted	$ 16.75	$ 1.08
Aggregate intrinsic value of stock options exercised (in thousands)	$ 3,764	$ -

Restricted stock awards

A summary of the Company's RSA activity is as follows:

	RSAs (in thousands)	Weighted-Average Grant Date Fair Value per Share
Unvested shares as of December 31, 2020	10,079	$ 0.33
Vested	(1,428)	0.25
Forfeited	(14)	0.68
Unvested shares as of March 31, 2021	8,637	$ 0.34

The fair value of vested RSAs was $0.4 million and $0.2 million for the three months ended March 31, 2021 and 2020, respectively.

14. Income taxes

The Company's income tax provision for interim periods is determined using an estimate of the Company's annual effective tax rate, adjusted for discrete items arising in the quarter. The Company's effective tax rate differs from the U.S. statutory tax rate primarily due to a valuation allowance on the deferred tax assets. Deferred tax assets and deferred tax liabilities are recognized based on temporary differences between the financial reporting and tax basis of assets and liabilities using statutory rates. A valuation allowance is recorded against deferred tax assets if it is more likely than not that some or all of the deferred tax assets will not be realized. Due to the uncertainty surrounding the realization of the favorable tax attributes in future tax returns, the Company has recorded a full valuation allowance against the Company's otherwise recognizable net deferred tax assets.

15. Net loss per share

Basic and diluted net loss per common share is calculated by dividing net loss by the weighted-average number of common shares outstanding during the period, without consideration for common stock equivalents. The Company was in a loss position for all periods presented, therefore basic net loss per share and diluted net loss per share are the same for all periods as the inclusion of all potential common securities outstanding would have been anti-dilutive.

The following table sets forth the computation of basic and diluted net loss per share of common stock:

	Three Months Ended March 31,	
	2021	2020
	(in thousands, except per share amounts)	
Net loss	$ (180,617)	$ (32,875)
Weighted-average shares outstanding, basic and diluted	119,131	10,820
Net loss per share, basic and diluted	$ (1.52)	$ (3.04)

The amounts in the table below were excluded from the calculation of diluted net loss per share due to their anti-dilutive effect:

	Three Months Ended March 31,	
	2021	2020
	(in thousands)	
Series A-1 convertible preferred stock	-	11,463
Series A-2 convertible preferred stock	-	95,427
Unvested restricted common stock	8,637	15,352
Options to purchase common stock	2,324	357
Unvested RSUs	325	345
Total	11,286	122,944

16. Employee benefit plan

In January 2019, the Company adopted a 401(k) retirement and savings plan (the 401(k) Plan) covering all employees. The 401(k) Plan allows employees to make pre- and post-tax contributions up to the maximum allowable amount set by the IRS. The Company has not made a matching contribution since plan inception.

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 together with our unaudited condensed consolidated financial statements and the related notes included elsewhere in this Quarterly Report on Form 10-Q and our audited consolidated financial statements and notes thereto and the related Management's Discussion and Analysis of Financial Condition and Results of Operations included as part of our 2020 Annual Report on Form 10-K as filed with the SEC on March 24, 2021 (2020 Form 10-K). This discussion and analysis and other parts of this Quarterly Report on Form 10-Q contain forward-looking statements based upon current beliefs, plans and expectations related to future events and our future financial performance that involve risks, uncertainties, and assumptions, such as statements regarding our intentions, plans, objectives, and expectations for our business. Our actual results and the timing of selected events could differ materially from those described in or implied by these forward-looking statements as a result of several factors, including those set forth in the section titled "Risk Factors." See also the section titled "Special Note Regarding Forward-Looking Statements."

Overview

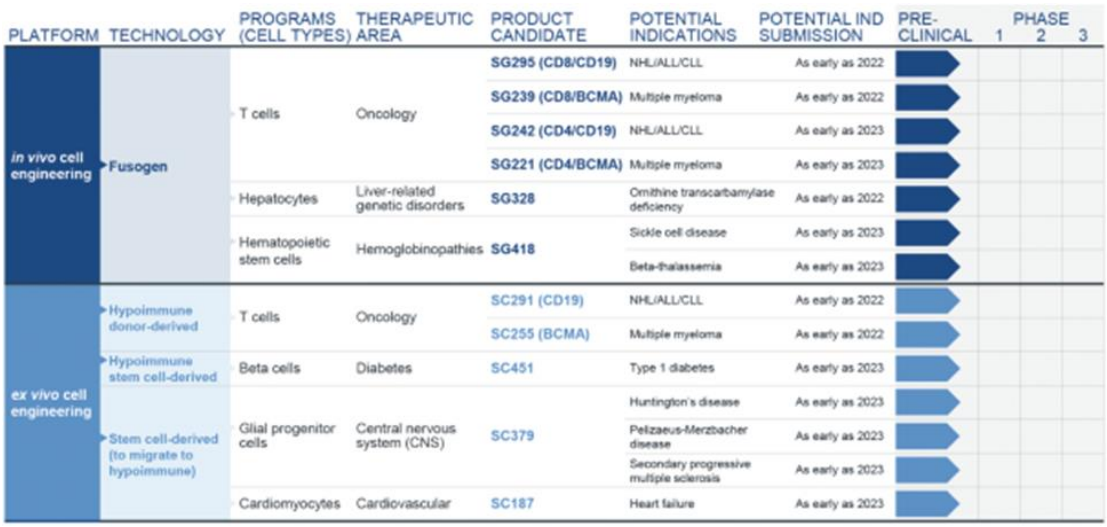
We were founded on the belief that engineered cells will be one of the most important transformations in medicine over the next several decades. The burden of diseases that can be addressed at their root cause through engineered cells is significant. We view engineered cells as having the potential to be as therapeutically disruptive as biologics to clinical practice. Our long-term aspirations are to be able to control or modify any gene in the body, to replace any cell that is damaged or missing, and to markedly improve access to cellular and gene-based medicines. We have brought together an experienced group of scientists, engineers, and company builders and combined them with the necessary technologies to move this vision forward. We are developing *in vivo* and *ex vivo* cell engineering platforms to revolutionize treatment across a broad array of therapeutic areas with unmet treatment needs, including oncology, diabetes, central nervous system disorders, cardiovascular diseases, and genetic disorders, among others. While our current product candidates are all in preclinical development, our goal is to file multiple investigational new drug applications (INDs) both in 2022 and 2023.

The process of repairing and controlling genes in the body, referred to as gene therapy or *in vivo* cell engineering, requires *in vivo* delivery of a therapeutic payload and modification of the genome. Of these, we believe delivery of a therapeutic payload represents the greatest unmet need and is thus at the core of our strategic focus, with our ultimate goal being the delivery of any payload to any cell in a specific and repeatable way. Our initial effort is on cell-specific delivery and increasing the diversity and size of payloads. Using our fusogen technology, we have shown in preclinical studies that we can specifically target numerous cell surface receptors that, when combined with delivery vehicles to form fusosomes, allow cell-specific delivery across multiple different cell types. We have initially chosen to focus this technology on delivering payloads to T cells, hepatocytes, and hematopoietic stem cells.

Frequently in disease, cells are damaged or missing entirely, and an effective therapy needs to replace the entire cell, an approach referred to as cell therapy or *ex vivo* cell engineering. A successful therapeutic requires an ability to manufacture cells at scale that engraft, function, and have the necessary persistence in the body. Of these, long-term persistence related to overcoming immunologic rejection of another person's cells has been the most challenging, which has led many to focus on autologous, or a patient's own, cells as the therapeutic source. However, autologous therapies require a complex process of harvesting cells from the patients, manipulating them outside the body, and returning them to the patient. Products utilizing this approach have had to manage significant challenges such as scalability, product variability, product quality, cost, patient accessibility, and a limited number of cell types being amenable to this approach. Given these limitations, rather than utilizing autologous cells to overcome immune rejection, we have invested in creating hypoimmune cells that can "hide" from the patient's immune system. We are striving to make therapies utilizing pluripotent stem cells with our hypoimmune genetic modifications as the starting material, which we then differentiate into a specific cell type, such as a pancreatic beta cell, before treating the patient. Additionally, for cell types for which effective differentiation protocols from a stem cell have not yet been developed, such as T cells, instead of starting from a pluripotent stem cell, we can utilize an allogeneic cell, differentiated cells sourced from a donor, as the starting material to which we then apply our hypoimmune genetic modifications.

We believe the time is right to develop engineered cell therapies across a broad range of therapeutic areas. Substantial progress in the understanding of genetics, gene editing, gene control, protein engineering, stem cell biology, immunology, process analytics, and computational biology have converged to create an opportunity to markedly increase the breadth and depth of the potential impact of genetic and cellular medicines. We are focused on creating transformative *in vivo* and *ex vivo* engineered cell therapies across a

range of therapeutic areas. We are in the early stages of development across a broad pipeline of product candidates, all of which are currently in the preclinical stage of development and are summarized below:



Our *ex vivo* and *in vivo* technology represents an aggregation of years of innovation and technology from multiple academic institutions and companies, including our fusogen technology acquired from Cobalt Biomedicines Inc. (Cobalt), our *ex vivo* cell engineering programs focused on replacing damaged cells in the heart and certain brain disorders acquired from Cytocardia Inc. and Oscine Corp., respectively, and hypoimmune technology licensed from the President and Fellows of Harvard College (Harvard) and The Regents of the University of California, amongst others. See Note 3, Acquisitions and Note 5, License and collaboration agreements, and to our consolidated financial statements included in the 2020 Form 10-K, as well as the subsection titled “Business— Key Intellectual Property Agreements” in Part I, Item 1, of our 2020 Form 10-K.

We were incorporated in July 2018 and our operations to date have included developing our *in vivo* and *ex vivo* cell engineering platforms, identifying and developing potential product candidates, executing preclinical studies, acquiring technology, organizing and staffing the company, business planning, establishing our intellectual property portfolio, raising capital, and providing general and administrative support for these operations. All of our programs are currently in the development stage, and we do not have any products approved for sale. Since our inception, we have incurred net losses each year. Our net losses were $180.6 million and $32.9 million for the three months ended March 31, 2021 and 2020, respectively. As of March 31, 2021, we had an accumulated deficit of $610.0 million. Our net losses resulted primarily from our research and development programs, and, to a lesser extent, general and administrative costs associated with our operations. In addition, the accumulated deficit of $610.0 million as of March 31, 2021 includes non-cash charges of $189.7 million and $82.0 million related to the revaluation of the success payment liabilities and contingent consideration, respectively.

In February 2021, we completed our initial public offering (IPO) and issued 27.0 million shares of our common stock, including 3.5 million shares pursuant to the full exercise of the underwriters’ option to purchase additional shares, at a price of $25.0 per share and received net proceeds of $626.4 million. Prior to the IPO, we funded our operations from the issuance and sale of our convertible preferred stock raising an aggregate of $705.5 million in gross proceeds. As of March 31, 2021, we had cash, cash equivalents, and marketable securities of $981.9 million. Based on our current operating plan, we believe that our existing cash, cash equivalents, and marketable securities will be sufficient to meet our working capital and capital expenditure needs for at least the next 36 months.

We anticipate that our expenses and operating losses will increase substantially over the foreseeable future. The expected increase in expenses will be driven in large part by our ongoing activities, if and as we: continue to advance our *in vivo* and *ex vivo* cell engineering platforms; continue preclinical development of our current and future product candidates and initiate additional preclinical studies; commence clinical studies of our current and future product candidates; establish our manufacturing capability, including developing our contract development and manufacturing relationships, and building our internal manufacturing facilities; acquire and license technologies aligned with our *in vivo* and *ex vivo* cell engineering platforms; seek regulatory approval of our current and future product candidates; expand our operational, financial, and management systems and increase personnel, including personnel to support our preclinical and clinical development, manufacturing, and commercialization efforts; continue to develop, grow, perfect, and defend our intellectual property portfolio; and incur additional legal, accounting, or other expenses in operating our business, including the additional costs associated with operating as a public company.

We are also investing early in building world class capabilities in key areas of manufacturing sciences and operations, including development of our *in vivo* and *ex vivo* cell engineering platforms, product characterization, and process analytics from the time candidates are in early research phases. Our investments also include scaled research solutions, scaled infrastructure, and novel technologies to improve efficiency, characterization, and scalability of manufacturing.

We anticipate that we will need to raise additional financing in the future to fund our operations, including the commercialization of any approved product candidates. Until such time, if ever, as we can generate significant product revenue, we expect to finance our operations with our existing cash, cash equivalents, and marketable securities, any future equity or debt financings, and upfront, milestone, and royalty payments, if any, received under future license or collaboration agreements. We may not be able to raise additional capital on terms acceptable to us or at all. If we are unable to raise additional capital when desired, our business, results of operations, and financial condition would be adversely affected.

COVID-19 business update

The global COVID-19 pandemic continues to evolve rapidly, and we will continue to monitor it closely. The extent of the impact of the COVID-19 pandemic on our business, operations, and clinical development timelines and plans remains uncertain and will depend on certain developments, including the duration and spread of the outbreak and its impact on our clinical trial enrollment, trial sites, contract research organizations (CROs), contract manufacturing organizations, and other third parties with whom we do business, as well as its impact on regulatory authorities and our key scientific and management personnel. We have experienced modest delays in our discovery and development activities as a result of the COVID-19 pandemic, primarily due to temporary and partial shutdowns at certain of our CROs and academic institutions that have since resumed operations, and due to the Washington, California, and Massachusetts stay-at-home orders where our operations are located. However, to the extent possible, we are conducting business as usual, with necessary or advisable modifications to employee travel and most of our non-laboratory employees working remotely. We will continue to actively monitor the situation related to COVID-19 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.

Acquisitions

We have completed various acquisitions since inception. For details regarding our acquisitions, see Note 3, Acquisitions, to our consolidated financial statements included in our 2020 Form 10-K, as well as the subsection titled “Business—Key Intellectual Property Agreements” in Part I, Item 1 of our 2020 Form 10-K.

License and collaboration agreements

We have entered into license and collaboration arrangements with various third parties. For details regarding these agreements, see Note 5, License and collaboration agreements, to our consolidated financial statements included in our 2020 Form 10-K, as well as the subsection titled “Business— Key Intellectual Property Agreements” in Part I, Item 1, of our 2020 Form 10-K.

Success payments and contingent consideration

Cobalt success payment and contingent consideration

Pursuant to the terms of the Cobalt acquisition agreement, we may be required to pay contingent consideration of up to an aggregate of $500.0 million upon the achievement of certain pre-specified development milestones (Cobalt Contingent Consideration), and a success payment of up to $500.0 million payable in cash or stock, at our discretion (the Cobalt Success Payment). The Cobalt Success Payment is payable, if at pre-determined valuation measurement dates, which are an IPO and periodically thereafter, our market capitalization equals or exceeds $8.1 billion, and we have a program based on the fusogen technology in a clinical trial pursuant to an IND, or have filed for, or received approval for, a biologics license application (BLA) or new drug application (NDA). A Cobalt Success Payment was not triggered upon the IPO. In addition to an IPO, a valuation measurement date is triggered upon a change of control when at least one of our programs based on the fusogen technology is the subject of an active research program. If there is a change of control and our market capitalization falls below certain thresholds on the change of control date, the amount of the potential Cobalt Success Payment will decrease, and the amount of potential Cobalt Contingent Consideration will increase. See Note 3, Acquisitions to our condensed consolidated financial statements included elsewhere in this report for details on the different market capitalizations and impact to the amount of the potential Cobalt Success Payment and potential Cobalt Contingent Consideration if there is a change of control.

As of March 31, 2021 and December 31, 2020, the estimated fair value of the Cobalt Success Payment liability was $156.5 million and $64.7 million, respectively, and are recorded in long-term liabilities on the condensed consolidated balance sheets. The estimated fair value of the Cobalt Contingent Consideration was $133.3 million and $121.9 million, respectively, and are recorded in long-term liabilities on the condensed consolidated balance sheets. For the three months ended March 31, 2021 and 2020, the Company recognized $91.8 million and $0.3 million in research and development expense in connection with the change in the estimated fair value of the Cobalt Success Payment, respectively, and $11.4 million and $0.4 million in research and development expense in connection with the change in fair value of the Cobalt Contingent Consideration, respectively. See Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations "—Critical accounting policies and significant judgments and estimates—Success payments" in our 2020 Form 10-K for more information on the accounting treatment of the Cobalt Success Payment.

Harvard success payments

Pursuant to the terms of the Harvard agreement, we may be required to make success payments up to an aggregate of $175.0 million, payable in cash, based on increases in the per share fair market value of our common stock (Harvard Success Payments). The potential Harvard Success Payments are based on multiples of increased value ranging from 5x to 40x based on a comparison of the per share fair market value of our common stock relative to the original issuance price of $4.00 per share at pre-determined valuation measurement dates. The Harvard Success Payments can be achieved over a maximum of 12 years from the effective date of the agreement. See Note 5, License and collaboration agreements to our unaudited condensed consolidated financial statements included elsewhere in this report for more details on the various per share common stock values that trigger a Harvard Success Payment.

We anticipate the first valuation measurement date to occur in February 2022, the one-year anniversary of our IPO, with valuation dates occurring periodically after this date. Additional valuation measurement dates are triggered by events which include: a merger, an asset sale, the sale of the majority of the shares held by Series A convertible preferred stockholders, and the last day of the term of the success payments. If a higher success payment tier is met at the same time a lower tier is met, both tiers will be owed. Any previous success payments made under the Harvard Agreement are credited against the success payment owed as of any valuation measurement date, so that Harvard does not receive multiple success payments in connection with the same threshold.

As of March 31, 2021 and December 31, 2020, the estimated fair value of the Harvard Success Payment liability was $35.7 million and $11.8 million, respectively. As of March 31, 2021 and December 31, 2020, $5.0 million and zero was recorded in short-term liabilities, and $30.7 million and $11.8 million were recorded in long-term liabilities in the condensed consolidated balance sheet, respectively. For the three months ended March 31, 2021 and 2020, we recognized $23.9 million and $0.2 million, respectively, in research and development expense in connection with the change in the estimated fair value of the Harvard Success Payment liability. See Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations "—Critical accounting policies and significant judgments and estimates—Success payments" in our 2020 Form 10-K for more information on the accounting treatment of the Harvard Success Payments.

Components of operating results

Operating expenses

Research and development

To date, research and development expenses have related primarily to discovery and development of our platform technology and product candidates. Research and development expenses are recognized as incurred and payments made prior to the receipt of goods or services to be used in research and development are recorded as prepaid expenses until the goods or services are received.

Research and development expenses consist of personnel-related costs, including salaries, benefits, and non-cash stock-based compensation, external research and development expenses incurred under arrangements with third parties, laboratory supplies, costs to acquire and license technologies aligned with our goal of translating engineered cells to medicines, facility and other allocated expenses, including rent, depreciation, and allocated overhead costs, and other research and development expenses.

Research and development expenses also include the change in the estimated fair value of our success payment liabilities and contingent consideration. Research and development expense related to our success payment liabilities and contingent consideration is unpredictable and may vary significantly from quarter to quarter and year to year due to changes in the assumptions used in the calculation. In addition, we may incur research and development expense to acquire and license technologies in the future, and the timing and amount of those expenses cannot be estimated with reliability and may also fluctuate from quarter to quarter and year to year.

We deploy our employee and infrastructure resources across multiple research and development programs for developing our *in vivo* and *ex vivo* cell engineering platforms, identifying and developing product candidates, and establishing manufacturing capabilities. Due to our early stage of development, number of ongoing projects, and our ability to use resources across several projects, the vast majority of our research and development costs are not recorded on a program-specific basis. These include costs for personnel, laboratory, and other indirect facility and operating costs.

Research and development activities account for a significant portion of our operating expenses. Excluding amounts attributable to changes in the estimated fair value of our success payment liabilities and contingent consideration, we anticipate that our research and development expenses will increase over the foreseeable future as we expand our research and development efforts including expanding the capabilities of our cell engineering platforms, identifying product candidates, completing preclinical studies and commencing clinical trials, seeking regulatory approval of our product candidates, and incurring costs to acquire and license technologies aligned with our goal of translating engineered cells to medicines. A change in the outcome of any of these factors could result in a significant change in the costs and timing associated with the development of our product candidates.

General and administrative

General and administrative expenses consist of personnel-related costs, including salaries, benefits, and non-cash stock-based compensation for our employees in finance, human resources, legal, information technology, executive, and other administrative functions, legal and consulting fees, recruiting costs, insurance fees, and facility costs not otherwise included in research and development expenses. Legal fees include those related to corporate and patent matters.

We anticipate that our general and administrative expenses will increase over the foreseeable future to support our continued research and development activities, grow our business, and support future possible business development opportunities. We also anticipate incurring additional expenses related to audit and legal services associated with operating as a public company, maintaining compliance with the rules and regulations of the Securities and Exchange Commission (SEC) and standards applicable to companies listed on a national securities exchange, investor relations activities, and other administrative and professional services.

Interest income, net

Interest income, net consists of interest earned on our cash, cash equivalents, and marketable securities.

Results of operations

Comparison of the three months ended March 31, 2021 and 2020

The following table summarizes our results of operations for the periods presented:

	Three Months Ended March 31,		
	2021	2020	Change
	(in thousands)		
Operating expenses:			
Research and development	$ 168,930	$ 27,320	$ 141,610
General and administrative	11,821	5,955	5,866
Total operating expenses	180,751	33,275	147,476
Loss from operations	(180,751)	(33,275)	(147,476)
Interest income, net	121	395	(274)
Other income, net	13	5	8
Net loss	$ (180,617)	$ (32,875)	$ (147,742)

Research and Development Expenses

The following table summarizes the components of our research and development expenses for the periods presented:

	Three Months Ended March 31,		
	2021	2020	Change
	(in thousands)		
Success payments	$ 115,657	$ 552	$ 115,105
Contingent consideration	11,393	362	11,031
Personnel	17,064	10,520	6,544
Research and laboratory	13,389	8,836	4,553
Facility and other allocated costs	9,456	6,059	3,397
Acquisition and licensing of technology	1,293	407	886
Other	678	584	94
Total research and development expense	$ 168,930	$ 27,320	$ 141,610

Research and development expenses were $168.9 million and $27.3 million for the three months ended March 31, 2021 and 2020, respectively. The increase of $141.6 million was primarily due to:

- a non-cash increase of $115.1 million for the change in the estimated fair value of our Cobalt and Harvard Success Payment liabilities in aggregate;
- a non-cash increase of $11.0 million for the change in the estimated fair value of the Cobalt Contingent Consideration;
- increased personnel-related expenses of $6.5 million, including non-cash stock-based compensation of $2.0 million, which was primarily attributable to an increase in headcount to expand our research and development capabilities;
- an increase of $4.6 million in research and laboratory costs, including preclinical studies, laboratory supplies, and other external research expenses; and
- an increase of $3.4 million of facility and other allocated costs, including rent, depreciation, and allocated overhead costs.

General and administrative Expenses

General and administrative expenses were $11.8 million and $6.0 million for the three months ended March 31, 2021 and 2020, respectively. The increase of $5.8 million was primarily due to increased personnel-related expenses of $2.5 million, including non-cash stock-based compensation of $1.4 million, primarily attributable to an increase in headcount to build our infrastructure, increased consulting and legal fees of $1.3 million, increased insurance of $1.1 million associated with being a public company, and facility costs including rent of $0.4 million.

Interest income, net

Interest income, net was $0.1 million and $0.4 million for the three months ended March 31, 2021 and 2020, respectively. The decrease of $0.3 million was due to lower interest rates on cash and marketable securities balances.

Liquidity, capital resources, and capital requirements

Sources of liquidity

As of March 31, 2021, we had $981.9 million in cash, cash equivalents, and marketable securities. To date we have raised an aggregate of approximately $1.3 billion in net proceeds, through our IPO and private placements of our convertible preferred stock. Since our inception, we have not generated any revenue from product sales or any other sources, and we have incurred significant operating losses. We have not yet commercialized any products and we do not expect to generate revenue from sales of any product candidates for a number of years, if ever.

Future funding requirements

We expect to incur additional losses in the foreseeable future as we conduct and expand our research and development efforts, including conducting preclinical studies and clinical trials, developing new product candidates, establishing internal and external manufacturing capabilities, and funding our operations generally.

Based on our current operating plan, we believe that our existing cash, cash equivalents, and marketable securities will be sufficient to meet our working capital and capital expenditure needs for at least the next 36 months. However, we anticipate that we will need to raise additional financing in the future to fund our operations, including the commercialization of any approved product candidates. We are subject to the risks typically related to the development of new products, and we may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors that may adversely affect our business.

Our future capital requirements will depend on many factors, including:

- the scope, timing, progress, costs, and results of discovery, preclinical development, and clinical trials for our current and future product candidates;
- the number of clinical trials required for regulatory approval of our current and future product candidates;
- the costs, timing, and outcome of regulatory review of any of our current and future product candidates;
- the cost of manufacturing clinical and commercial supplies of our current and future product candidates;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales, and distribution, for any of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property rights, and defending any intellectual property-related claims, including any claims by third parties that we are infringing upon their intellectual property rights;
- our ability to maintain existing, and establish new, strategic collaborations, licensing, or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty, or other payments due under any such agreement;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- expenses to attract, hire, and retain skilled personnel;
- the costs of operating as a public company;
- our ability to establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from third-party and government payers;
- addressing any potential interruptions or delays resulting from factors related to the COVID-19 pandemic;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products, and technologies.

Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations from the sale of additional equity or debt financings, or other capital which may come in the form of strategic collaborations, licensing, or other arrangements. In the event that additional financing is required, we may not be able to raise it on terms acceptable to us, or at all. If we raise additional funds through the issuance of equity or convertible debt securities, it may result in dilution to our existing stockholders. Debt financing, if available, may result in increased fixed payment obligations, and the existence of securities with rights that may be senior to those of our common stock. If we incur indebtedness, we could become subject to covenants that would restrict our operations. If we raise funds through strategic collaborations, licensing or other arrangements, we may relinquish significant rights or grant licenses on terms that are not favorable to us. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic and otherwise. If we are unable to raise additional capital when desired, our business, results of operations, and financial condition would be adversely affected.

Cash flows

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

	Three Months Ended March 31,	
	2021	2020
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (49,913)	$ (29,547)
Investing activities	49,091	39,181
Financing activities	626,703	2
Net increase in cash, cash equivalents, and restricted cash	$ 625,881	$ 9,636

Operating activities

During the three months ended March 31, 2021, net cash used in operating activities was $49.9 million, consisting primarily of our net loss of $180.6 million and the change in our net operating assets and liabilities of $3.1 million, partially offset by non-cash charges of $133.8 million. The non-cash charges of $133.8 million consisted primarily of $115.7 million for revaluation of our success payment liabilities, $11.4 million for revaluation of contingent consideration, non-cash stock-based compensation expense of $4.2 million, depreciation expense of $2.2 million, and other non-cash charges of $0.3 million.

During the three months ended March 31, 2020, net cash used in operating activities was $29.5 million, consisting primarily of our net loss of $32.9 million and the change in our net operating assets and liabilities of $1.1 million, partially offset by non-cash charges of $4.4 million. The non-cash charges of $4.4 million consisted of depreciation expense of $1.3 million, $0.9 million for revaluation of success payments and contingent liabilities, non-cash stock-based compensation expense of $0.8 million, and other non-cash charges of $1.4 million.

Investing activities

During the three months ended March 31, 2021 and 2020, cash provided by investing activities was $49.1 million and $39.2 million, respectively. This consisted primarily of sales and maturities, less purchases, of marketable securities of $55.5 million and $44.8 million, offset by purchases of property and equipment of $6.4 million and $5.6 million for the three months ended March 31, 2021 and 2020, respectively.

Financing activities

During the three months ended March 31, 2021, cash provided by financing activities was $626.7 million, consisting primarily of net proceeds from our IPO of $626.4 million. During the three months ended March 31, 2020, cash provided by financing activities was immaterial.

Contractual obligations and commitments

The following table summarizes our significant contractual obligations and commitments as of March 31, 2021:

	Payments Due by Period				
	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years	Total
Operating leases	$ 10,300	$ 31,524	$ 31,284	$ 42,616	$ 115,724

Other than as disclosed in the table above, the payment obligations under our license, collaboration, and acquisition agreements as of March 31, 2021 are contingent upon future events such as our achievement of pre-specified development, regulatory, and commercial milestones, or royalties on net product sales. See the section titled “Business—Key Intellectual Property Agreements” in Part I, Item 1, of our 2020 Form 10-K, for more information about these payment obligations. We are also obligated to make a success payment to Cobalt of up to $500.0 million, payable in cash or stock at our discretion, pursuant to the terms and conditions in the Cobalt acquisition agreement, and success payments to Harvard up to an aggregate of $175.0 million, payable in cash. See Part II, Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations “—Critical accounting policies and significant judgments and estimates—Success payments” in our 2020 Form 10-K for more information on the success payments. As of March 31, 2021, the timing and likelihood of achieving the milestones and success payments and generating future product sales are uncertain and therefore, any related payments are not included in the table above.

We also enter into agreements in the normal course of business for sponsored research, preclinical studies, contract manufacturing, and other services and products for operating purposes, which are generally cancelable upon written notice. These obligations and commitments are not included in the table above.

Off-balance sheet arrangements

Since our inception, we have not engaged in any off-balance sheet arrangements as defined under the rules and regulations of the SEC.

JOBS Act accounting election

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (the JOBS Act). We will cease to be an emerging growth company until the earliest of (1) December 31, 2026, (2) the last day of the fiscal year in which we have total annual gross revenue of at least $1.07 billion, (3) the last day of the fiscal year in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the fair market value of our common stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year, or (4) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on certain exemptions from various public company reporting requirements, including not being required to have our internal control over financial reporting by our independent registered public accounting firm pursuant to Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments not previously approved. In addition, 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 the extended transition period for any new or revised accounting standards during the period in which we remain an emerging growth company; however, we may adopt certain new or revised accounting standards early if the standard allows early adoption.

Critical accounting policies and significant judgements and estimates

Our condensed consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. 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. The critical accounting policies used in preparation of these condensed consolidated financial statements as of March 31, 2021 and for the three months ended March 31, 2021 and 2020 are consistent with those discussed in Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations "—Critical accounting policies and significant judgments and estimates" in our 2020 Form 10-K.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risks in the ordinary course of our business, primarily related to interest rate sensitivities and the volatility of our stock price.

Interest Rate Risk

As of March 31, 2021, we had cash, cash equivalents, and restricted cash of $752.8 million, which consisted of bank deposits and money market funds. We also had marketable securities of $231.2 million as of March 31, 2021. The primary objective of our investment activities is to preserve capital to fund our operations while earning a low risk return. Because our marketable securities are primarily short-term in duration, we believe that our exposure to interest rate risk is not significant, and a hypothetical 10% change in market interest rates during any of the periods presented would not have had a significant impact on the total value of our portfolio. We had no debt outstanding as of March 31, 2021.

Foreign Currency

Our functional currency is the U.S. dollar. We are exposed to foreign currency rate risk related to various third-party service contracts denominated in foreign currencies. Transaction gains and losses are included in other income (expense), net on our statements of operations and were not material for any of the periods presented. A hypothetical 10% change in exchange rates during any of the periods presented would not have had a material impact on our financial statements.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor. We believe that inflation has not had a material effect on our financial statements.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As of March 31, 2021, management, with the participation of our Chief Executive Officer and Chief Financial Officer, have evaluated our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including the Chief Executive Officer and the Chief Financial Officer, to allow timely decisions regarding required disclosures.

Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of March 31, 2021, the design and operation of our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting during the quarter ended March 31, 2021, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently a party to any material legal proceedings. From time to time, we may, however, in the ordinary course of business face various claims brought by third parties, and we may, from time to time, make claims or take legal actions to assert our rights, including intellectual property rights as well as claims relating to employment matters and the safety or efficacy of our products. Any of these claims could subject us to costly litigation, and, while we generally believe that we have adequate insurance to cover many different types of liabilities, our insurance carriers may deny coverage, may be inadequately capitalized to pay on valid claims, or our policy limits may be inadequate to fully satisfy any damage awards or settlements. If this were to happen, the payment of any such awards could have a material adverse effect on our operations, cash flows and financial position. Additionally, any such claims, whether or not successful, could damage our reputation and business.

Item 1A. Risk Factors

Investing in shares of our common stock involves a high degree of risk. You should carefully consider the following risks and uncertainties, together with all of the other information contained in this Quarterly Report on Form 10-Q, including our financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q, before making an investment decision. The risks described below are not the only ones facing us. Many of the following risks and uncertainties are, and will be, exacerbated by the COVID-19 pandemic and any worsening of the global business and economic environment as a result. The occurrence of any of the following risks, or of additional risks and uncertainties not presently known to us or that we currently believe to be immaterial, could materially and adversely affect our business, financial condition, reputation, or results of operations. In such case, the trading price of shares of our common stock could decline, and you may lose all or part of your investment.

Summary Risk Factors

The summary risk factors set forth below are the principal risks that we believe are material to our investors and a reader should carefully consider them. The following is a summary of the principal risks and uncertainties; however, there are additional risk and uncertainties described this "Risk factors" section. This summary does not address every aspect of our risks factors, all of the risks that we face, or other factors not presently known to us or that we currently believe are immaterial.

The following is a summary of the principal risks and uncertainties described in more detail in this Quarterly Report:

- We are a preclinical-stage biotechnology company and have incurred significant losses since our inception, and we expect to incur losses for the foreseeable future. We have no products approved for commercial sale and may never achieve or maintain profitability.
- Our limited operating history may make it difficult for you to evaluate our prospects and likelihood of success.
- Our *in vivo* and *ex vivo* cell engineering platforms are based on novel technologies that are unproven and may not result in approvable or marketable products, which exposes us to unforeseen risks and makes it difficult for us to predict the time and cost of product development and potential for regulatory approval, and we may not be successful in our efforts to use and expand our technology platforms to build a pipeline of product candidates.
- All of our product candidates are in preclinical development and have not commenced clinical development. Preclinical and clinical drug development is a lengthy and expensive process with uncertain timelines and uncertain outcomes. If preclinical studies or clinical trials of a product candidate are prolonged or delayed, we may be unable to obtain required regulatory approvals, and therefore be unable to commercialize our product candidates on a timely basis or at all.
- The development and commercialization of biopharmaceutical products is subject to extensive regulation, and the regulatory approval processes of the U.S. Food and Drug Administration (FDA) and comparable foreign authorities are lengthy, time-consuming, and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates on a timely basis if at all, our business will be substantially harmed.
- Our clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of our product candidates or any future product candidates, which would prevent or delay or limit the scope of regulatory approval and commercialization.
- We may encounter difficulties in managing our growth, which could disrupt our operations.
- The outbreak of the novel coronavirus disease, COVID-19, could materially and adversely affect our preclinical studies and development, any clinical trials we subsequently commence, and our business, financial condition, and results of operations.

- We will require additional funding in order to finance operations. If we are unable to raise capital when needed, or on acceptable terms, we could be forced to delay, reduce, or eliminate our product development programs or commercialization efforts.
- Our success payment and contingent consideration obligations may result in dilution to our stockholders, may be a drain on our cash resources, or may cause us to incur debt obligations to satisfy the payment obligations.
- If we are unable to successfully identify, develop, and commercialize any product candidates, or experience significant delays in doing so, our business, financial condition, and results of operations will be materially adversely affected.
- Our success depends on our ability to protect our intellectual property and our proprietary technologies.
- We depend on intellectual property licensed from third parties and if we breach our obligations under these agreements or if any of these agreements is terminated, we may be required to pay damages, lose our rights to such intellectual property and technology, or both, which would harm our business.
- While we believe our pipeline will yield multiple investigational new drug applications (INDs), we may not be able to file INDs to commence clinical trials on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed.

Risks Related to Our Limited Operating History, Financial Condition and Need for Additional Capital

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

We are a preclinical-stage biotechnology company with a limited operating history. Biotechnology product development is a highly speculative undertaking and involves a substantial degree of risk. We have incurred significant losses since inception, have not generated any revenue from product sales, and have financed our operations principally through private financings. We expect that it will be several years, if ever, before we have a commercialized product and generate revenue from product sales. Our net losses were $180.6 million and $32.9 million for the three months ended March 31, 2021 and 2020, respectively. As of March 31, 2021, we had an accumulated deficit of $610.0 million. Our losses have resulted principally from expenses incurred for the research and development of our *in vivo* and *ex vivo* cell engineering platforms, and from management and administrative costs and other expenses that we have incurred while building our business infrastructure.

We expect our expenses and operating losses will continue to increase substantially for the foreseeable future as we expand our research and development efforts, expand the capabilities of our cell engineering platforms, identify product candidates, complete preclinical studies and commence clinical trials, seek regulatory approval and commercialization of our product candidates, and operate as a public company. We anticipate that our expenses will increase substantially as we:

- continue to advance our *in vivo* and *ex vivo* cell engineering platforms;
- continue preclinical development of our current and future product candidates and initiate additional preclinical studies;
- commence clinical studies of our current and future product candidates;
- establish our manufacturing capability, including developing our contract development and manufacturing organization (CDMO) relationships and building our internal manufacturing facilities;
- acquire and license technologies aligned with our *in vivo* and *ex vivo* cell engineering platforms;
- seek regulatory approval of our current and future product candidates;
- expand our operational, financial, and management systems and increase personnel, including personnel to support our preclinical and clinical development, manufacturing, and commercialization efforts;
- continue to develop, perfect, and defend our intellectual property portfolio; and
- incur additional legal, accounting, or other expenses in operating our business, including the additional costs associated with operating as a public company.

We have devoted a significant portion of our financial resources and efforts to building our organization, developing our *in vivo* and *ex vivo* cell engineering platforms, identifying and developing potential product candidates, executing preclinical studies, acquiring technology, organizing and staffing the company, business planning, establishing our intellectual property portfolio, raising capital, and providing general and administrative support for these operations. We are in the early stages of development of our product candidates, have not yet commenced any clinical trials for any of our product candidates, and have not completed development and commercialization of any product candidate.

To become and remain profitable, we must succeed in identifying, developing, getting regulatory approval for and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our product candidates, continuing to discover and develop additional product candidates, obtaining regulatory approval for any product candidates that successfully complete clinical trials, accessing manufacturing capacity, establishing marketing capabilities, commercializing and ultimately selling any products for which we may obtain regulatory approval. We may never succeed in any or all of these activities and, even if we do, we may never generate revenue that is sufficient to achieve profitability. Even if we do achieve profitability, we may not be able to sustain profitability or meet outside expectations for our profitability. If we are unable to achieve or sustain profitability or to meet outside expectations for our profitability, the value of our shares of common stock could be materially adversely affected.

Because of the numerous risks and uncertainties associated with pharmaceutical products and biological development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we are required by the FDA or comparable foreign regulatory authorities to perform studies in addition to those we currently anticipate, or if there are any delays in commencing or completing our clinical trials or the development of any of our product candidates, our expenses could increase and commercial revenue could be further delayed and more uncertain, which will have a material adverse impact on our business.

We will require additional funding in order to finance operations. If we are unable to raise capital when needed, or on acceptable terms, we could be forced to delay, reduce, or eliminate our product development programs or commercialization efforts.

Developing biopharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception, and we expect our expenses to increase in connection with our ongoing activities, particularly as we conduct clinical trials of, and seek regulatory and marketing approval for, our product candidates. Even if one or more of our product candidates is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. To date, we have funded our operations primarily through private financings. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the preclinical development of our *in vivo* and *ex vivo* platforms and product candidates, commence clinical studies for any product candidates, initiate clinical trials, and continue to research, develop, and conduct preclinical studies of other potential product candidates.

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

As of March 31, 2021, we had $981.9 million in cash, cash equivalents, and marketable securities. Based on our current business plans, we believe that our existing cash, cash equivalents and marketable securities at March 31, 2021, will be sufficient to fund our operating expenses and capital expenditure requirements for at least the next 36 months. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect, requiring us to seek additional funds sooner than planned, through public or private equity or debt financings or other sources, such as strategic collaborations. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop our product candidates. Our future capital requirements will depend on many factors, including:

- the scope, timing, progress, costs, and results of discovery, preclinical development, and clinical trials for our current or future product candidates;
- the number of clinical trials required for regulatory approval of our current or future product candidates;
- the costs, timing, and outcome of regulatory review of any of our current or future product candidates;
- the cost of manufacturing clinical and commercial supplies of our current or future product candidates;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales, and distribution, for any of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property rights, and defending any intellectual property-related claims, including any claims by third parties that we are infringing upon their intellectual property rights;

- our ability to maintain existing, and establish new, strategic collaborations, licensing, or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty, or other payments due under any such agreement;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- expenses to attract, hire, and retain skilled personnel;
- the costs of operating as a public company;
- our ability to establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from third-party and government payers;
- addressing any potential interruptions or delays resulting from factors related to the COVID-19 pandemic;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products, and technologies.

Our ability to raise additional funds will depend on financial, economic, political and market conditions and other factors, over which we may have no or limited control. Market volatility resulting from the COVID-19 pandemic or other factors could also adversely impact our ability to access capital as and when needed. Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we could be required to:

- delay, limit, reduce, or terminate preclinical studies, clinical trials, or other research and development activities, or eliminate one or more of our development programs altogether; and
- delay, limit, reduce, or terminate our efforts to access manufacturing capacity, establish sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates, or reduce our flexibility in developing or maintaining our sales and marketing strategy.

Our success payment and contingent consideration obligations in our license and acquisition agreements may result in dilution to our stockholders, may be a drain on our cash resources, or may cause us to incur debt obligations to satisfy the payment obligations.

We agreed to make success payments in cash pursuant to our license agreement with the President and Fellows of Harvard College (Harvard) and contingent consideration and success payments, payable in cash or stock at our discretion, pursuant to the terms and conditions of our acquisition agreement with Cobalt Biomedicine, Inc. (Cobalt). The success payments to Harvard (Harvard Success Payments) are based on increases in the fair value of our common stock. The potential Harvard Success Payments are based on multiples of increased value ranging from 5x to 40x based on a comparison of the per share fair value of our common stock relative to the original $4.00 issuance price at pre-determined valuation measurement dates. The amount of the Harvard Success Payments does not exceed an aggregate of $175.0 million which would only occur upon a 40x increase in value. The Harvard Success Payments can be achieved over a maximum of 12 years from the effective date of the agreement. The valuation measurement dates for the Harvard Success Payments are triggered by events which include: the one-year anniversary of an IPO, and periodically thereafter, a merger, an asset sale, the sale of the majority of the shares held by our Series A convertible preferred stockholders, and the last day of the term of the success payments. If a higher success payment tier is met at the same time a lower tier is first met, both tiers will be owed. Any previous success payments made to Harvard are credited against the success payment owed as of any valuation measurement date so that Harvard does not receive multiple success payments in connection with the same threshold.

The contingent consideration related to the Cobalt acquisition (Cobalt Contingent Consideration) is up to an aggregate of $500.0 million upon the achievement of certain pre-defined development milestones. The success payment to Cobalt (Cobalt Success Payment) of $500.0 million is payable if, at pre-determined valuation measurement dates, which are an IPO and periodically thereafter, our market capitalization equals or exceeds $8.1 billion, and we have a program based on the fusogen technology in a clinical trial pursuant to an IND, or have filed for, or received approval for, a biologics license application (BLA) or new drug application (NDA). In addition to an IPO, a valuation measurement date is triggered upon a change of control when at least one of our programs based on the fusogen technology is the subject of an active research program. If there is a change of control and market capitalization falls below $8.1 billion the amount of the potential Cobalt Success Payment will decrease and the amount of potential Cobalt Contingent Consideration will increase. The term of the Cobalt Success Payment is 20 years from the date of acquisition. See Note 3, Acquisitions, to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for details on the different Company valuation thresholds and impact to the value of the potential Cobalt Success Payment and potential Cobalt Contingent Consideration if there is a change of control.

In order to satisfy our obligations to make these success payments, if and when they are triggered, we may issue equity or convertible debt securities that may cause dilution to our stockholders, or we may use our existing cash or incur debt obligations to satisfy the success payment obligation in cash, which may adversely affect our financial position. In addition, these success payments may impede our ability to raise money in future public offerings of debt or equity securities or to obtain a third party line of credit. We expect the first valuation measurement date for the Harvard Success Payments to be the one-year anniversary of an IPO. See Note 5, License and collaboration agreements, to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for the per share common stock prices that trigger a Harvard Success Payment and the corresponding payment amount. We did not owe a Cobalt Success Payment based on the mere occurrence of our IPO. The first valuation measurement date for the Cobalt Success Payment was our IPO, but our IPO did not trigger such a payment. We do not expect to owe a Cobalt Success Payment within one year of our IPO. However, such payment is dependent on our progress on fusogen-related product candidates and our market capitalization, which is unpredictable and may fluctuate significantly from quarter to quarter and year to year.

The contingent consideration and success payment obligations in our license and acquisition agreements may cause operating results to fluctuate significantly from quarter to quarter and year to year, which may reduce the usefulness of our financial statements.

Our success payment and contingent consideration obligations under our license and acquisition agreements are recorded as liabilities on our condensed consolidated balance sheets. Under U.S. generally accepted accounting principles (GAAP), we are required to estimate the fair value of these liabilities as of each quarter end, with changes in the estimated fair value recorded in research and development expense. Factors that may lead to increases or decreases in the estimated fair value of the success payment liabilities include, among others, changes in the value of our common stock and market capitalization, changes in volatility, the estimated number and timing of valuation measurement dates, the term of the success payments, and changes in the risk-free interest rate. Factors that may lead to increases or decreases in the estimated fair value of contingent consideration include, among others, the estimated likelihood and timing in which milestones may be achieved and the estimated discount rates. As of March 31, 2021 and December 31, 2020, the estimated fair value of the Cobalt Success Payment liability was $156.5 million and $64.7 million, respectively, and the estimated fair value of the Harvard Success Payment liability was $35.7 million and $11.8 million, respectively. As of March 31, 2021 and December 31, 2020, the estimated fair value of the Cobalt Contingent Consideration was $133.3 million and $121.9 million, respectively. A small change in the inputs and related assumptions for success payment liabilities and contingent consideration may have a relatively large change in the estimated valuation and associated liabilities and resulting expense or gain. As a result, our operating results and financial condition as reported by GAAP may fluctuate significantly from quarter to quarter and year to year and may reduce the usefulness of our GAAP financial statements. For example, for the Harvard Success Payments, keeping all other variables constant, a hypothetical 20% increase in our common stock price at March 31, 2021 from $33.47 per share to $40.16 per share would have increased the expense recorded in the three months ended March 31, 2021 associated with the success payment liability by $7.4 million. A hypothetical 20% decrease in the stock price from $33.47 per share to $26.78 per share would have decreased the expense recorded in three months ended March 31, 2021 associated with the success payment liability by $7.9 million. For the Cobalt Success Payment, keeping all other variables constant, a hypothetical 20% increase in our market capitalization at March 31, 2021 from $6.3 billion to $7.5 billion would have increased the expense recorded in the three months ended March 31, 2021 associated with the success payment liability by $23.7 million. A hypothetical 20% decrease in our market capitalization from $6.3 billion to $5.0 billion would have decreased the expense recorded in three months ended March 31, 2021 associated with the success payment liability by $27.3 million.

Our limited operating history may make it difficult for you to evaluate our prospects and likelihood of success.

We are a preclinical-stage biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. Since our inception in July 2018, we have devoted substantially all of our resources and efforts to building our organization, developing our *in vivo* and *ex vivo* cell engineering platforms, identifying and developing potential product candidates, executing preclinical studies, acquiring technology, organizing and staffing the company, business planning, establishing and securing our intellectual property portfolio, raising capital, and providing general and administrative support for these operations. All of our product candidates are still in preclinical stage of development, we have not yet demonstrated our ability to successfully commence or complete any clinical trials (including Phase 3 or other pivotal clinical trials), obtain regulatory approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Additionally, we expect our financial condition and operating results to continue to fluctuate significantly from period to period due to a variety of factors, many of which are beyond our control. Consequently, any predictions you may make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by preclinical-stage biopharmaceutical companies in rapidly evolving fields. We also may need to transition from a company with a research focus to a company capable of supporting commercial activities. If we do not adequately address these risks and difficulties or successfully make such a transition, it could have a material adverse impact on our business.

Risks Related to Our Business

Our in vivo and ex vivo platforms are based on novel technologies that are unproven and may not result in approvable or marketable products, which exposes us to unforeseen risks and makes it difficult for us to predict the time and cost of product development and potential for regulatory approval, and we may not be successful in our efforts to use and expand our technology platforms to build a pipeline of product candidates.

We are seeking to identify and develop a broad pipeline of product candidates using our *in vivo* and *ex vivo* cell engineering platforms. We have not commenced clinical trials for any product candidates developed with these platforms. The scientific research that forms the basis of our efforts to develop product candidates with our platforms is still ongoing. We are not aware of any FDA approved therapeutics utilizing fusogen technology or that are iPSC-derived cell products. Further, the scientific evidence to support the feasibility of developing therapeutic treatments based on our platforms is both preliminary and limited. As a result, we are exposed to a number of unforeseen risks and it is difficult to predict the types of challenges and risks that we may encounter during development of our product candidates. For example, we have not tested any of the product candidates being developed using our cell engineering platforms in humans, and our current data is limited to animal models and preclinical cell lines, the results of which may not translate into humans. Further, relevant animal models and assays may not accurately predict the safety and efficacy of our product candidates in humans, and we may encounter significant challenges creating appropriate models and assays for demonstrating the safety and purity of our product candidates. In addition, our fusogen and hypoimmune technologies have potential safety risks related to, but not limited to, genotoxicity associated with the delivery of genome modifying payloads. For example, DNA sequences that randomly integrate into a cell's DNA may increase risk for or cause certain cancers. Alternatively, targeted gene-editing approaches may edit the genome at sites other than the targeted DNA or cause DNA rearrangements, each of which may have oncogenic or other adverse effects. Furthermore, our hypoimmune technology has potential safety risks related to, but not limited to, the potential risk of a hypoimmune cell becoming infected with a virus or undergoing oncogenic transformation. Also, our stem cell-based product candidates have potential safety risks related to, but not limited to, the potential risk of insufficient cell differentiation leading to oncogenic transformations or other adverse effects. As a result, it is possible that safety events or concerns could negatively affect the development of our product candidates, including adversely affecting patient enrollment among the patient populations that we intend to treat.

Given the novelty of our technologies, we intend to work closely with the FDA and comparable foreign regulatory authorities to perform the requisite scientific analyses and evaluation of our methods to obtain regulatory approval for our product candidates; however, due to a lack of comparable experiences, the regulatory pathway with the FDA and comparable regulatory authorities may be more complex and time-consuming relative to other more well-known therapeutics. Even if we obtain human data to support our product candidates, the FDA or comparable foreign regulatory agencies may lack experience in evaluating the safety and efficacy of our product candidates developed using our platforms, which could result in a longer than expected regulatory review process, increase our expected development costs, and delay or prevent commercialization of our product candidates. The validation process takes time and resources, may require independent third-party analyses, and may not be accepted or approved by the FDA and comparable foreign regulatory authorities. We cannot be certain that our approach will lead to the development of approvable or marketable products, alone or in combination with other therapies.

Additionally, a key element of our strategy is to use and expand our *in vivo* and *ex vivo* cell engineering platforms to build a pipeline of product candidates and progress those product candidates through clinical development for the treatment of a variety of different types of diseases. Although our research and development efforts to date have been focused on identifying a pipeline of product candidates directed at various disease types, we may not be able to develop product candidates that are safe and effective. Even if we are successful in building our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be approvable or marketable products that will receive marketing approval and achieve market acceptance. If we do not continue to successfully develop, get approval for and begin to commercialize any product candidates, we will face difficulty in obtaining product revenue in future periods, which could result in significant harm to our financial position and adversely affect our share price.

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

Our ability to generate revenue from sales of any of our approved product candidates, which we do not expect will occur for at least the next several years, if ever, will depend heavily on the successful identification, development, regulatory approval and eventual commercialization of any product candidates, which may never occur. We have never generated revenue from sales of any products, and we may never be able to develop, obtain regulatory approval for or commercialize a marketable product. We are in preclinical development and all of our product candidates will require significant clinical development; management of preclinical, clinical and manufacturing activities; regulatory approval in multiple jurisdictions; establishing manufacturing supply, including

commercial manufacturing supply; and require us to build a commercial organization and make substantial investment and significant marketing efforts before we generate any revenue from product sales. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates.

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

- successful and timely completion of preclinical studies and clinical trials for which the FDA, or any comparable foreign regulatory authority, agree with the design, endpoints, or implementation;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- receiving regulatory approvals or authorizations for conducting future clinical trials;
- initiation and successful patient enrollment in, and completion of, clinical trials on a timely basis;
- our ability to demonstrate to the satisfaction of the FDA or any comparable foreign regulatory authority that the applicable product candidate is safe and efficacious as a treatment for our targeted indications or, in the case of an applicable product candidate which is regulated as a biological product, that the applicable product has suitable purity and is safe and potent for our targeted indications;
- our ability to demonstrate to the satisfaction of the FDA or any comparable foreign regulatory authority that the applicable product candidate's risk-benefit ratio for its proposed indication is acceptable;
- timely receipt of marketing approvals for our product candidates from applicable regulatory authorities;
- addressing any potential interruptions or delays resulting from factors related to the COVID-19 pandemic;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities; and
- establishing, scaling up and scaling out, either alone or with third-party manufacturers, manufacturing capabilities of clinical supply for our clinical trials and commercial manufacturing (including licensure), if any of our product candidates are approved.

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

Additionally, clinical or regulatory setbacks to other companies developing similar products or within adjacent fields, including those in gene editing and gene therapy and allogenic cell-based therapies, may impact the clinical development of and regulatory pathway for our current or future product candidates, or may negatively impact the perceptions of value or risk of our technologies.

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

We have experienced rapid growth since our inception in July 2018. As of December 31, 2018, we had 37 full-time employees and, as of March 31, 2021, we grew to 282 full-time employees. We expect continued growth in the number of our employees and the scope of our operations, particularly to continue our IND-enabling studies, establish regulatory, quality, and clinical operations, and begin manufacturing supply chain logistics.

To manage our anticipated future growth, we will continue to implement and improve our managerial, operational, and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the complexity in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. In addition, we have limited experience in managing the manufacturing processes necessary for making cell and gene therapies. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

In addition, future growth imposes significant added responsibilities on members of management, including: identifying, recruiting, integrating, maintaining, and motivating additional employees; managing our internal development efforts effectively, including the clinical and FDA review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and improving our operational, financial and management controls, reporting systems, and procedures.

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

The outbreak of the novel coronavirus disease, COVID-19, could materially and adversely affect our preclinical studies and development, any clinical trials we subsequently commence, and our business, financial condition, and results of operations.

In December 2019, the coronavirus disease, COVID-19, was identified in Wuhan, China. Since then, COVID-19 has spread globally. In March 2020, the World Health Organization declared COVID-19 a global pandemic and the United States declared a national emergency with respect to COVID-19. In response to the COVID-19 pandemic, "shelter in place" orders and other public health guidance measures have been implemented across much of the United States, including in the locations of our offices and those of key vendors and partners. As a result of the COVID-19 pandemic, or similar pandemics, and related "shelter in place" orders and other public health guidance measures, we have and may in the future experience disruptions that could materially and adversely impact our preclinical studies and development, any clinical trials we subsequently commence, and our business, financial condition, and results of operations. In response to the spread of COVID-19, we have closed our executive offices with our administrative employees continuing their work outside of our offices and limited the number of staff in any given research and development laboratory and have taken other precautionary measures as well, including the periodic testing of our employees. We also established a cross-functional task force and implemented business continuity plans designed to address and mitigate the impact of the ongoing COVID-19 pandemic on our business. Potential disruptions to our preclinical development efforts include, but are not limited to:

- delays or disruptions in preclinical experiments and IND-enabling studies due to restrictions of on-site staff, limited or no access to animal facilities, and unforeseen circumstances at contract research organizations (CROs) and vendors;
- limitations on employee or other resources that would otherwise be focused on the conduct of our preclinical work and any clinical trials we subsequently commence, including because of sickness of employees or their families, the desire of employees to avoid travel or contact with large groups of people, an increased reliance on working from home, school closures, or mass transit disruptions;
- delays in necessary interactions with regulators, ethics committees, and other important agencies and contractors due to limitations in employee resources or forced furlough of government or contractor personnel; and
- limitations in maintaining our corporate culture that facilitates the transfer of institutional knowledge within our organization and fosters innovation, teamwork, and a focus on execution.

We have experienced delays in the procurement of certain laboratory supplies, such as cell culture plasticware and single use containers, as a result of increased demand due to ramp up of COVID-19 research and manufacturing, government-mandated allocation of materials for COVID-19 research and manufacturing, and delays in vendors increasing manufacturing capacity to address increased demand.

We have not yet commenced clinical trial activities for any of our product candidates. If we commence clinical trials for one or more of our product candidates, potential disruptions of those clinical activities as a result of COVID-19 or similar pandemics include, but are not limited to:

- interruption of key clinical trial activities, such as clinical trial site data monitoring and efficacy, safety and translational data collection, processing and analyses, due to limitations on travel imposed or recommended by federal, state, or local governments, employers and others or interruption of clinical trial subject visits, which may impact the collection and integrity of subject data and clinical study endpoints;
- delays or difficulties in initiating or expanding clinical trials, including delays or difficulties with clinical site initiation and recruiting clinical site investigators and clinical site staff;
- delays or difficulties in enrolling and retaining patients in our clinical trials;
- increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting COVID-19 or other health conditions or being forced to quarantine;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns, or stoppages and disruptions in materials and reagents;

- 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 or delays in the operations of the FDA and comparable foreign regulatory agencies;
- changes in regulations as part of a response to the COVID-19 pandemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- refusal of the FDA or comparable regulatory authorities to accept data from clinical trials in affected geographies; and
- additional delays, difficulties or interruptions as a result of current or future shutdowns due to the COVID-19 pandemic in countries where we or our third-party service providers operate.

The COVID-19 global pandemic continues to rapidly evolve. Although many countries, including certain countries in Europe and the United States, have re-opened, rises in new cases have caused certain countries to re-initiate restrictions. The extent to which the outbreak may affect our preclinical studies, clinical trials, business, financial condition, and results of operations will depend on future developments, which are highly uncertain and cannot be predicted at this time, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions, and actions to contain the outbreak or treat its impact, such as social distancing and quarantines or lock-downs in the United States and other countries, business closures, or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. Additionally, we are unable to predict if a different pandemic could have similar or different impacts on our business, financial condition, or share price. Future developments in these and other areas present material uncertainty and risk with respect to our clinical trials, business, financial condition, and results of operations.

Our ability to develop our cell engineering platforms and products and our future growth depends on retaining our key personnel and recruiting additional qualified personnel.

Our success depends upon the continued contributions of our key management, scientific, and technical personnel, many of whom have been instrumental for us and have substantial experience with our cell engineering platforms, underlying technologies and related product candidates. Given the specialized nature of our *in vivo* and *ex vivo* cell engineering and the fact that these are novel and emerging fields, there is an inherent scarcity of experienced personnel in these fields. As we continue developing our product candidates in our pipeline, we will require personnel with medical, scientific, or technical qualifications specific to each program. The loss of key managers and senior scientists could delay our research and development activities. Despite our efforts to retain valuable employees, members of our management, scientific, and development teams may terminate their employment with us on short notice. Although we have employment agreements with certain of our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. Further, certain of our key employees, including Drs. Fry, Goldman and Murry, retain partial employment at academic institutions; Dr. Goldman currently devotes approximately 60% of his time to the University of Rochester and the University of Copenhagen, Dr. Murry currently devotes approximately 25% to his time to the University of Washington, and Dr. Fry currently devotes approximately 25% of his time to the University of Colorado until August 2021 when Dr. Fry plans to devote 100% of his time to us. These arrangements may expose us to increased potential for these individuals to return to their academic positions full-time or devote less of their attention to us than is optimal, and, potentially, expose us to claims of intellectual property ownership or co-ownership by the respective academic institutions. The competition for qualified personnel in the biotechnology and pharmaceutical industries is intense, and our future success depends upon our ability to attract, retain, and motivate highly skilled scientific, technical, and managerial employees. We face competition for personnel from other companies, universities, public and private research institutions, and other organizations. If our recruitment and retention efforts are unsuccessful in the future, it may be difficult for us to implement our business strategy, which could have a material adverse effect on our business.

In addition, our research and development programs, clinical operations and sales and marketing efforts depend on our ability to attract and retain highly skilled scientists, engineers and sales professionals. Competition for skilled personnel in our market is intense, and we have from time to time experienced, and we expect to continue to experience, difficulty in hiring and retaining employees with appropriate qualifications on acceptable terms, or at all. Many of the companies with which we compete for experienced personnel

have greater resources than we do, and any of our employees may terminate their employment with us at any time. If we hire employees from competitors or other companies, their former employers may attempt to assert that these employees or we have breached legal obligations, resulting in a diversion of our time and resources and, potentially, damages. In addition, job candidates and existing employees often consider the value of the stock awards they receive in connection with their employment. If the perceived benefits of our stock awards decline, it may harm our ability to recruit and retain highly skilled employees. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business and future growth prospects would be harmed.

While we believe our pipeline will yield multiple INDs, we may not be able to file INDs to commence clinical trials on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed.

We expect our pipeline to yield multiple INDs beginning as early as 2022, including INDs for our fusosome CAR T product candidates from our *in vivo* cell engineering platform and our allogeneic CAR T cell product candidates from our *ex vivo* cell engineering platform. We cannot be sure that submission of an IND will result in the FDA allowing testing and clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such clinical trials. The manufacturing of our product candidates, including our CAR T *ex vivo* cell engineering product candidates, remains an emerging and evolving field. Accordingly, we expect chemistry, manufacturing and control related topics, including product specifications, will be a focus of IND reviews, which may delay the clearance of INDs. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or clinical trial application, we cannot guarantee that such regulatory authorities will not change their requirements in the future.

We may not realize the benefits of technologies that we have acquired, or will acquire in the future, or other strategic transactions that we have or will consummate.

Our *in vivo* and *ex vivo* cell engineering technology represents an aggregation of years of innovation and technology from multiple academic institutions and companies, including our fusogen technology acquired from Cobalt, our *ex vivo* cell engineering programs focused on replacing damaged cells in the heart and certain brain disorders acquired from Cytocardia Inc. (Cytocardia) and Oscine Corp. (Oscine), respectively, and hypoimmune technology licensed from Harvard and The Regents of the University of California (UCSF), amongst others. Further, a key component of our strategy is to acquire and in-license technologies to support our mission of using engineered cells as medicines. As such, we actively evaluate various strategic transactions on an ongoing basis. We may acquire other businesses, products or technologies, as well as pursue joint ventures or investments in complementary businesses. The success of our strategic transactions and any future strategic transactions depends on the risks and uncertainties involved including:

- unanticipated liabilities related to acquired companies or joint ventures;
- difficulties integrating acquired personnel, technologies, and operations into our existing business;
- retention of key employees;
- diversion of management time and focus from operating our business to management of acquisition and integration efforts, strategic alliances or joint ventures challenges;
- increases in our expenses and reductions in our cash available for operations and other uses;
- disruption in our relationships with collaborators or suppliers as a result of such a transaction;
- possible write-offs or impairment charges relating to acquired businesses or joint ventures; and
- challenges resulting from the COVD-19 pandemic making it more difficult to integrate acquisitions into our business.

If any of these risks or uncertainties occur, we may not realize the anticipated benefit of any acquisition or strategic transaction. Additionally, foreign acquisitions and joint ventures are subject to additional risks, including those related to integration of operations across different cultures and languages, currency risks, potentially adverse tax consequences of overseas operations, and the particular economic, political and regulatory risks associated with specific countries.

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 intend to build and operate our own manufacturing facility, which will require significant resources, and we may fail to successfully operate our facility, which could adversely affect our clinical trials and the commercial viability of our product candidates.

The manufacture of biopharmaceutical products is complex and requires significant expertise, including the development of advanced manufacturing techniques and process controls. Manufacturers of *ex vivo* cell engineering products often encounter difficulties in production, particularly in scaling up, scaling out, validating initial production, ensuring the absence of contamination, and ensuring process robustness after initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state, and foreign regulations. As a result of the complexities, the cost to manufacture biologics in general, and our cell-based product candidates in particular, is generally higher than traditional small molecule chemical compounds, and the manufacturing process is less reliable and is more difficult to reproduce. The application of new regulatory guidelines or parameters, such as those related to control strategy testing, may also adversely affect our ability to manufacture our product candidates.

A key to our strategy is operating our own manufacturing facility. We are investing early in building world class capabilities in key areas of manufacturing sciences and operations, including development of our *in vivo* and *ex vivo* cell engineering platforms, product characterization, and process analytics from the time candidates are in early research phases. Our investments also include scaled research solutions, scaled infrastructure, and novel technologies to improve efficiency, characterization, and scalability of manufacturing. However, we have limited experience in managing the manufacturing processes necessary for making cell and gene therapies. We cannot be sure that the manufacturing processes employed by us or the technologies that we incorporate for manufacturing will result in viable or scalable yields of *in vivo* and *ex vivo* cell engineering product candidates that will be safe, be effective, and meet market demand. Any commercial manufacturing facilities we build will also require FDA or comparable foreign regulatory authority approval, which we may never obtain. Even if approved, we would be subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Administration, corresponding state agencies, and comparable foreign regulatory authority to ensure strict compliance with current good manufacturing practices (cGMPs), current good tissue practices (cGTPs) and other government regulations. We also may make changes to our manufacturing process at various points during development, and even after commercialization, for various reasons, such as controlling costs, achieving scale, decreasing processing time, increasing manufacturing success rate, or other reasons. Such changes carry the risk that they will not achieve their intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of our ongoing clinical trials, future clinical trials, or the performance of the product, once commercialized. In some circumstances, changes in the manufacturing process may require us to perform 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. We may also make further changes to our manufacturing process before or after commercialization, and such changes may require us to show the comparability of the resulting product to the product used in the clinical trials using earlier processes. We may be required to collect additional clinical data from any modified process prior to obtaining marketing approval for the product candidate produced with such modified process. If clinical data are not ultimately comparable to that seen in the earlier trials in terms of safety or efficacy, we may be required to make further changes to our process and/or undertake additional clinical testing, either of which could significantly delay the clinical development or commercialization of the associated product candidate.

Furthermore, if contaminants are discovered in our supply of product candidates or in the manufacturing facilities, such supply may have to be discarded and our manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any stability or other issues relating to the manufacture of our product candidates will not occur in the future. We may not be able to manufacture our product candidates as a result of not meeting regulatory requirements and may not be able to scale up or scale out our manufacturing to meet market demand.

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

Because we have limited financial and managerial resources, we focus on research programs, therapeutic platforms, and product candidates that we identify for specific indications. Additionally, we have contractual commitments under our collaboration agreements to use commercially reasonable efforts to develop certain programs and, thus, do not have unilateral discretion to vary from such agreed to efforts. In addition, we have contractual commitments to conduct certain development plans, and thus may not have discretion to modify such development plans, including clinical trial designs, without agreement from our collaboration partners. As a result, we may forego or delay pursuit of opportunities with other therapeutic platforms or product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs, therapeutic platforms, and product candidates for specific indications may not yield any commercially viable products. If

we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing, or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

The use of human stem cells exposes us to a number of risks in the development of our human stem cell derived products, including restrictions on the use of human stem cells, as well as ethical, legal and social implications of research on the use of stem cells, any of which could prevent us from completing the development or gaining acceptance for commercially viable products derived from human stem cells.

We use human stem cells in our research and development, including embryonic stem cells (ESCs), and one or more of our *ex vivo* cell engineering product candidates may be derived from human stem cells. The use of such cells in our research, or as starting cell lines in the manufacture of one or more of our product candidates, exposes us to a number of risks. These risks include securing sufficient and viable stem cells as starting material, potential difficulties in recruiting patients for our trials, as well as managing a multitude of legal and regulatory restrictions on the sourcing and use of these cells. In particular, in some states, use of embryonic tissue as a source of stem cells is prohibited and many research institutions have adopted policies regarding the ethical use of human embryonic tissue. If these policies or restrictions have the effect of limiting the scope of research conducted using our stem cells, our ability to develop our *ex vivo* cell engineering product candidates may be impaired and could have an adverse material effect on our business. Further, the use of stem cells, and particularly embryonic stem cells, has social, legal and ethical implications. Certain political and religious groups continue to voice opposition to the use of human stem cells in drug research, development, and manufacture. Adverse publicity due to ethical and social controversies surrounding the use of stem cells could lead to negative public opinion, difficulties enrolling patients in our clinical trials, increased regulation and stricter policies regarding the use of such cells, which could harm our business and may limit market acceptance of our product candidates. In addition, clinical experience with stem cells, including induced pluripotent stem cells (iPSCs) and ESCs, is limited. We are not aware of any products that utilize iPSCs or ESCs as a starting material that have received marketing approval from the FDA or a comparable foreign regulatory body. Therefore, we may experience unexpected side effects or unexpected regulatory delays during clinical trials, prior to approval, or after regulatory approval if an approval were to occur. Furthermore, our *ex vivo* stem cell-derived products will rely on starting materials donated by human sources. If the consent, authorization or process for the donation of those materials is not obtained or conducted in accordance with applicable legal, ethical or regulatory requirements, we could face delays in the clinical testing and approval of these products, or, potentially, we could face claims by such human sources which could expose us to damages.

Negative public opinion and increased regulatory scrutiny of research and therapies involving gene editing or other in vivo or ex vivo cell engineering technologies may damage public perception of our product candidates or adversely affect our ability to conduct our business or obtain regulatory approvals for our product candidates.

Certain aspects of our cell engineering platforms rely on the ability to edit genes. Public perception may be influenced by claims that gene editing is unsafe, and products incorporating gene editing may not gain the acceptance of the public or the medical community. In particular, our success will depend upon physicians specializing in our targeted diseases prescribing our product candidates as treatments in lieu of, or in addition to, existing, more familiar, treatments for which greater clinical data may be available. Any increase in negative perceptions of gene editing may result in fewer physicians prescribing our treatments or may reduce the willingness of patients to utilize our treatments or participate in clinical trials for our product candidates. In addition, given the novel nature of *in vivo* and *ex vivo* cell engineering technologies, governments may place import, export or other restrictions in order to retain control or limit the use of the technologies. Increased negative public opinion or more restrictive government regulations either in the United States or internationally, would have a negative effect on our business or financial condition and may delay or impair the development and commercialization of our product candidates or demand for such product candidates.

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

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

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

Success in preclinical studies does not ensure that later preclinical studies or clinical trials will be successful. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in clinical trials, even after positive results in earlier preclinical studies. These setbacks have been caused by, among other things, preclinical findings made while clinical

trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. The design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses. Notwithstanding any potential promising results in earlier studies, we cannot be certain that we will not face similar setbacks. In addition, the results of our preclinical animal studies, including our non-human primate studies, may not be predictive of the results of outcomes in subsequent clinical trials on human subjects. Product candidates in clinical trials may fail to show the desired pharmacological properties or safety and efficacy traits despite having progressed through preclinical studies.

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

All of our product candidates are in preclinical development and have not commenced clinical development. Preclinical and clinical drug development is a lengthy and expensive process with uncertain timelines and uncertain outcomes. If preclinical studies or clinical trials of a product candidate are prolonged or delayed, we may be unable to obtain required regulatory approvals, and therefore be unable to commercialize our product candidates on a timely basis or at all.

Preclinical studies and clinical testing are expensive and can take many years to complete, and their outcomes are inherently uncertain. Failure can occur at any time during this process. Product candidates in later stages of clinical trials may fail to produce the same results or to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Our future clinical trial results may not be successful.

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

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

- delays in or failure to obtain regulatory authorization to commence a trial;
- delays in or failure to obtain institutional review board, or IRB, approval at each site;
- delays in or failure to reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- difficulty in recruiting clinical trial investigators of appropriate competencies and experience;
- lack of sufficient availability of donor material suitable from eligible and qualified donors for certain of our product candidates for the manufacture of product candidates from our *ex vivo* cell engineering platform;
- delays in establishing the appropriate dosage levels in clinical trials;
- delays in or failure to recruit and enroll suitable patients to participate in a trial, particularly considering study inclusion and exclusion criteria and patients' prior lines of therapy and treatment;
- the difficulty in certain countries in identifying the sub-populations that we are trying to treat in a particular trial, which may delay enrollment and reduce the power of a clinical trial to detect statistically significant results;
- lower than anticipated retention rates of patients in clinical trials;
- failure to have patients complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a trial;
- delays adding new investigators or clinical trial sites;
- safety or tolerability concerns could cause us or governmental authorities, as applicable, to suspend or terminate a trial if it is found that the participants are being exposed to unacceptable health risks, undesirable side effects, or other

unfavorable characteristics of the product candidate, or if such undesirable effects or risks are found to be caused by a chemically or mechanistically similar therapeutic or therapeutic candidate;

- our third-party research contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- changes in regulatory requirements, policies, and guidelines;
- manufacturing sufficient quantities of a product candidate for use in clinical trials;
- the quality or stability of a product candidate falling below acceptable standards;
- changes in the treatment landscape for our target indications that may make our product candidates no longer relevant;
- third-party actions claiming infringement by our product candidates in clinical trials outside the United States and obtaining injunctions interfering with our progress; and
- business interruptions resulting from geo-political actions, including war and terrorism, natural disasters including earthquakes, typhoons, floods, and fires, or disease, including the COVID-19 pandemic.

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

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

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

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

To obtain the requisite regulatory approvals to market and sell any of our product candidates and any other future product candidates, we must demonstrate through clinical trials that our product candidates are safe and effective for use in each targeted

indication. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical development process. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful, and a clinical trial can fail at any stage of testing.

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

Clinical trials that we conduct may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols, and the rate of dropout among clinical trial participants. If the results of our ongoing or future clinical trials are inconclusive with respect to the efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may be delayed in obtaining marketing approval, if at all. Additionally, any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications.

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

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

From time to time, we may publicly disclose interim, topline, or preliminary data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. Further, modifications or improvements to our manufacturing processes for a therapy may result in changes to the characteristics or behavior of the product candidate that could cause our product 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 or interim data from 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 product candidate, and our company in general. If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, any of our potential product candidates may be harmed, which could harm our business, operating results, prospects, or financial condition.

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

Undesirable side effects that may be caused by our product candidates could cause us or regulatory authorities to interrupt, delay, or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign authorities. We have not commenced clinical trials for any of our product candidates, and we do not have any clinical data to fully anticipate side effects. Accordingly, we may experience unexpected side effects and/or higher levels of known side effects in clinical trials, including adverse events known in the classes of therapeutics. These include the potential for, among others, infusion reaction, cytokine release syndrome (CRS), graft-versus-host disease (GvHD), neurotoxicities and certain cancers.

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

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

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

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

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

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

Our product candidates are considered to be biologics and the process of manufacturing biologics is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls.

We do not yet own or operate any cGMP manufacturing facilities. We rely, and expect for some period of time to continue to rely, on third-party contract development and manufacturing organizations for the manufacture of our product candidates for preclinical and clinical testing. To date, we and our contract manufacturers have limited experience in the technology transfer of manufacturing processes from us to our contract manufacturers and the manufacturing of cGMP batches of our product candidates. Our contract manufacturers must comply with cGMPs, regulations, and guidelines for the manufacturing of biologics used in clinical trials and, if approved, marketed products. To date, we have not scaled the manufacturing process for later-stage clinical trials and commercialization. Larger scale manufacturing will require the development of new processes, including for the removal of impurities that are a normal byproduct of the manufacturing process. The nature of our product candidates requires the development of novel manufacturing processes and analytical technologies, which could cause delays in the scaling of manufacturing, as well as greater costs that could negatively impact the financial viability of our product candidates. We cannot be sure that the manufacturing processes employed by our third-party manufacturers or the technologies that our third-party manufacturers incorporate for manufacturing will result in viable or scalable yields of *in vivo* and *ex vivo* cell engineering product candidates that will be safe, be effective, and meet market demand.

The process of manufacturing our biologic product candidates is extremely susceptible to product loss due to contamination, equipment failure, or improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics, and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, and other supply disruptions. If microbial, viral, or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, this could lead to withdrawal of our products from clinical trials and the market, and such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Moreover, if the FDA or comparable foreign regulatory authorities determine that our third-party manufacturers are not in compliance with laws and regulations, including those governing cGMPs, the FDA or comparable foreign regulatory authority may not approve a Biologics License Application (BLA), marketing authorisation application (MAA), or comparable authorization until the deficiencies are corrected or we replace the manufacturer in our applications with a manufacturer that is in compliance. Third-party manufacturers may not be able to manufacture our product candidates as a result of not meeting regulatory requirements.

Any adverse developments affecting manufacturing operations for our product candidates, if any are approved, may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our products. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications as a result of defects or storage over an extended period of time, undertake costly remediation efforts, or seek more costly manufacturing alternatives. As part of our process development efforts, we also may make changes to our manufacturing processes at various points during development, for various reasons, such as controlling costs, achieving scale, decreasing processing time, increasing manufacturing success rate, or other reasons. Such changes carry the risk that they will not achieve their intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of our ongoing clinical trials or future clinical trials. In some circumstances, changes in the manufacturing process may require us to perform comparability studies and to collect additional data from patients prior to undertaking more advanced clinical trials.

We are exposed to a number of risks related to our supply chain for the materials required to manufacture our product candidates.

Manufacturing our product candidates is highly complex and requires sourcing specialty materials. Many of the risks associated with the complexity of manufacturing our final products are applicable to the manufacture and supply of the raw materials. In particular, these starting materials are subject to inconsistency in yields, variability in characteristics, contamination, difficulties in scaling the production process and defects. Similar minor deviations in the manufacturing process for these starting materials could result in supply disruption and reduced production yields for our final product. In addition, we rely on third parties for the supply of these materials exposing us to similar risks of reliance on third parties as described above with respect to the manufacturing and supply of our drug products.

Our manufacturing processes requires many reagents, which are drug substance intermediates used in our manufacturing processes to bring about chemical or biological reactions, and other specialty materials and equipment, some of which are manufactured or supplied by small companies with limited resources and experience to support commercial biologics production. We currently depend on a limited number of vendors for certain materials and equipment used in the manufacture of our product candidates. Some of these suppliers may not have the capacity to support commercial products manufactured under cGMP by biopharmaceutical firms or may otherwise be ill-equipped to support our needs. Reagents and other key materials from these suppliers may have inconsistent attributes and introduce variability into our manufactured product candidates, which may contribute to variable patient outcomes and possible adverse events. We also do not have supply contracts with many of these suppliers and may not be able to obtain supply contracts with them on acceptable terms or at all. Accordingly, we may experience delays in receiving key materials and equipment to support clinical or commercial manufacturing.

For some of these reagents, equipment, and materials, we rely and may in the future rely on sole source vendors or a limited number of vendors. An inability to continue to source product from any of these suppliers, which could be due to regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands, or quality issues, could adversely affect our ability to satisfy demand for our product candidates, which could adversely and materially affect our product sales and operating results or our ability to conduct clinical trials, either of which could significantly harm our business.

As we continue to develop and scale our manufacturing process, we expect that we will need to obtain rights to and supplies of certain materials and equipment to be used as part of that process. We may not be able to obtain rights to such materials on commercially reasonable terms, or at all, and if we are unable to alter our process in a commercially viable manner to avoid the use of such materials or find a suitable substitute, it would have a material adverse effect on our business. Even if we are able to alter our process so as to use other materials or equipment, such a change may lead to a delay in our clinical development and/or commercialization plans. If such a change occurs for product candidate that is already in clinical testing, the change may require us to perform both comparability studies and to collect additional data from patients prior to undertaking more advanced clinical trials.

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

Successful and timely completion of clinical trials will require that we enroll and retain a sufficient number of patient candidates. Any clinical trials we conduct may be subject to delays for a variety of reasons, including as a result of patient enrollment taking longer than anticipated, patient withdrawal, or adverse events. These types of developments could cause us to delay the trial or halt further development.

Our clinical trials will compete with other clinical trials that are in the same therapeutic areas as our product candidates, and this competition reduces the number and types of patients available to us, as some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Moreover, enrolling patients in clinical trials for diseases in which there is an approved standard of care is challenging, as patients will first receive the applicable standard of care. Many patients who respond positively to the standard of care do not enroll in clinical trials. This may limit the number of eligible patients able to enroll in our clinical trials who have the potential to benefit from our product candidates and could extend development timelines or increase costs for these programs. Patients who fail to respond positively to the standard of care treatment will be eligible for clinical trials of unapproved drug candidates. However, these prior treatment regimens may render our therapies less effective in clinical trials.

Because the number of qualified clinical investigators and clinical trial sites is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites.

Patient enrollment depends on many factors, including:

- the size and nature of the patient population;
- the severity of the disease under investigation;
- eligibility criteria for the trial;
- the proximity of patients to clinical sites;
- the design of the clinical protocol;
- the ability to obtain and maintain patient consents;
- perceived risks and benefits of the product candidate under evaluation, including any perceived risks associated with iPSC-derived product candidates;
- the ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the risk that patients enrolled in clinical trials will drop out of the trials before the administration of our product candidates or trial completion;
- the availability of competing clinical trials;
- the availability of such patients during the COVID-19 pandemic;

- the availability of new drugs approved for the indication the clinical trial is investigating; and
- clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies.

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

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

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

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

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

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

Risks Related to Our Regulatory Environment

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

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

We have not previously submitted a BLA to the FDA or similar regulatory approval filings to comparable foreign authorities, for any product candidate, and we cannot be certain that any of our product candidates will receive regulatory approval. We are not permitted to market our product candidates in the United States or in other countries until we receive approval of a BLA from the

FDA or marketing approval from applicable regulatory authorities outside the United States. Obtaining approval of a BLA can be a lengthy, expensive, and uncertain process, and as a company we have no experience with the preparation of a BLA submission or any other application for marketing approval. Further, the FDA has not yet granted approval for a therapeutics derived from stem cells, which we believe may increase the complexity, uncertainty and length of the regulatory approval process for certain of our product candidates derived from our *ex vivo* cell engineering platform. In addition, the FDA has the authority to require a risk evaluation and mitigation strategies, or REMS, plan as part of a BLA or after approval, which may impose further requirements or restrictions on the distribution or use of an approved biologic, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry.

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

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

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

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Notably, to date, the FDA has required that any patient receiving a gene therapy be followed for 15 years post-treatment. This post-treatment follow-up increases the cost and complexity of commercializing gene therapy products. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

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

If the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, testing, labeling, packaging, distribution, import, export, adverse event reporting, storage, advertising, promotion, and recordkeeping

for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval, all of which may result in significant expense and limit our ability to commercialize such products. In addition, any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations, as well as, for the manufacture of certain of our product candidates, the FDA's cGTPs for the use of human cellular and tissue products to prevent the introduction, transmission or spread of communicable diseases. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP, cGTPs and adherence to commitments made in any approved marketing application. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, quality control, and distribution.

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

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

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning letters;
- issue, or require us to issue, safety-related communications, such as safety alerts, field alerts, "Dear Doctor" letters to healthcare professionals, or import alerts;
- impose civil or criminal penalties;
- suspend, limit, or withdraw regulatory approval;
- suspend any of our preclinical studies and clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;

- impose restrictions on our operations, including closing our and our contract manufacturers' facilities; or
- seize or detain products, refuse to permit the import or export of products, or require us to conduct a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products, if approved. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

Moreover, the policies of the FDA and of comparable foreign regulatory authorities may change and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these orders will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose restrictions on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. In addition, if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

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

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

Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or comparable foreign regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or comparable foreign regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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

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

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

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

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving, or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under any U.S. federal healthcare program, such as Medicare and Medicaid. The term "remuneration" has been broadly interpreted to include anything of value, including stock options. The federal Anti-Kickback Statute has also been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other hand. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. Any arrangements with prescribers must be for *bona fide* services and compensated at fair market value. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal civil and criminal false claims laws, including without limitation, the civil False Claims Act, which can be enforced by private citizens on behalf of the U.S. federal government through civil whistleblower or *qui tam* actions, and the federal civil monetary penalties law which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease, or conceal an obligation to pay money to the U.S. federal government. Pharmaceutical manufacturers can cause false claims to be presented to the U.S. federal government by, among other things, engaging in impermissible marketing practices, such as the off-label promotion of a product for an indication for which it has not received FDA approval. Further, pharmaceutical manufacturers can be held liable under the civil False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items, or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation;
- the U.S. Federal Food, Drug, and Cosmetic Act (the FDCA), which prohibits, among other things, the adulteration or misbranding of drugs, biologics, and medical devices;
- the U.S. Public Health Service Act, which prohibits, among other things, the introduction into interstate commerce of a biological product unless a biologics license is in effect for that product;
- the U.S. Physician Payments Sunshine Act and its implementing regulations, which requires, among other things, certain manufacturers of drugs, devices, biologics, and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare and Medicaid Services, or CMS, information related to certain payments and other transfers of value to physicians, as defined by statute, and teaching hospitals, as well as ownership and investment interests held by such physicians and

their immediate family members. Beginning in 2022, such obligations will include the reporting of payments and other transfers of value provided in the previous year to certain other healthcare professionals, including physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants, and certified nurse-midwives;

- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements, and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and state and local laws requiring the registration of pharmaceutical sales representatives; and
- similar healthcare laws and regulations in foreign jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is not always possible to identify and deter employee misconduct or business noncompliance, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. We have entered into consulting and scientific advisory board arrangements with physicians and other healthcare providers, including some who could influence the use of our product candidates, if approved. Compensation under some of these arrangements includes the provision of stock or stock options in addition to cash consideration. Because of the complex and far-reaching nature of these laws, it is possible that governmental authorities could conclude that our payments to physicians may not be fair market value for *bona fide* services or that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal, and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of noncompliance, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

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

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

If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material and adverse effect on our business, financial condition, results of operations and prospects, including the

imposition of significant civil, criminal and administrative penalties, damages, monetary fines, individual imprisonment, disgorgement of profits, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of noncompliance with the law, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and pursue our strategy.

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

In the United States and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, was enacted, which substantially changed the way healthcare is financed by both governmental and private payors. Among the provisions of the ACA of importance to the pharmaceutical and biotechnology industries, which includes biologics, are the following:

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

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For example, legislation enacted in 2017 informally titled the Tax Cuts and Jobs Act of 2017, repealed the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage that is commonly referred to as the "individual mandate." In December 2019, a U.S. District Court upheld a ruling that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. In March 2020, the Supreme Court of the United States agreed to hear the appeal of this decision, but it is uncertain when the Supreme Court will rule on this case. It is unclear how this and other efforts to challenge, repeal, or replace the ACA will impact the ACA or our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted which, among other things, have reduced Medicare payments to several types of providers, including hospitals and cancer treatment centers. These new laws or any other similar laws introduced in the future, as well as regulatory actions that may be taken by CMS, may result in additional reductions in Medicare and other healthcare funding, which could negatively affect our customers and accordingly, our financial operations. Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives.

Additionally, individual states in the United States have passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing and costs. Similar developments have occurred outside of the United States, including in the European Union where healthcare budgetary constraints have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. To obtain reimbursement or pricing approval in some European Union member states, we may be required to conduct studies that compare the cost-effectiveness of our product candidates to other therapies that are considered the local standard of care.

It is also possible that additional governmental action is taken in response to address the COVID-19 pandemic. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action in the United States, particularly as a result of the recent presidential election, or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

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

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

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

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

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

Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Third-party payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Decisions regarding the extent of coverage and amount of

reimbursement to be provided for any product candidates that we develop will be made on a payor-by-payor basis. One payor's determination to provide coverage for a drug does not assure that other payors will also provide coverage and adequate reimbursement for the drug. Additionally, a third-party payor's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved.

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

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

Our inability to promptly obtain coverage and adequate reimbursement from both third-party payors for the product candidates that we may develop and for which we obtain regulatory approval could have a material and adverse effect on our business, financial condition, results of operations, and prospects.

We face potential liability related to the privacy of personal information, including health information we utilize in the development of products developed from our ex vivo cell engineering platform, as well as information we obtain from clinical trials sponsored by us from research institutions and directly from individuals.

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

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

Certain of the research materials we use in our therapeutic research and development efforts, as well as stem cell lines used as starting material in our *ex vivo* cell engineering product candidates are derived from human sources, which potentially contain sensitive identifiable personal information regarding the donor. In addition, once we commence clinical trials, we may maintain sensitive identifiable personal information, including health information, that we receive throughout the clinical trial process, in the course of our research collaborations, and directly from individuals (or their healthcare providers) who enroll in our patient assistance programs. As such, we may become subject to further obligations under HIPAA. In addition, our collection of personal information generally (e.g., of employees currently and/or of patients in the future) may subject us to state data privacy laws governing the processing of personal information and requiring notification of affected individuals and state regulators in the event of a breach of such personal information. These state laws include the California Consumer Privacy Act (CCPA) and its related regulations, and (once effective) the recently approved California Privacy Rights Act amending the CCPA which establish additional data privacy rights for residents of the State of California, with corresponding obligations on businesses related to transparency, deletion rights, and opt-out of the selling of personal information, and grants a private right of action for individuals in the event of certain security breaches. Similar laws relating to data privacy and security have been proposed in other states and at the federal level, and if passed, such laws may have potentially conflicting requirements that would make compliance challenging, require us to expend significant resources to come into compliance, and restrict our ability to process certain personal information.

Further, California voters approved a new privacy law, the California Privacy Rights Act, or CPRA, in the November 3, 2020 election. Effective starting on January 1, 2023, the CPRA will significantly modify the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. The CPRA also creates a new state agency that will be vested with authority to implement and enforce the CCPA and the CPRA. New legislation proposed or enacted in various other states will continue to shape the data privacy environment nationally. Certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to confidential, sensitive and personal information than federal, international or other state laws, and such laws may differ from each other, which may complicate compliance efforts.

Any clinical trial programs and research collaborations that we engage in outside the United States may implicate international data protection laws, including, in Europe, the General Data Protection Regulation (GDPR). The GDPR imposes stringent operational requirements for data processors and controllers of personal data. Among other things, the GDPR requires detailed notices for clinical trial subjects and investigators, as well as the security of personal data, and notification of data processing obligations or security incidents to appropriate data protection authorities or data subjects. Further, following the United Kingdom's withdrawal from the European Union effective as of December 31, 2020, we will have to comply with the GDPR and the GDPR as incorporated into United Kingdom national law, which may have differing requirements.

One particularly sensitive issue under these European Union data privacy laws involves European Economic Area (EEA) laws on data export if we begin to transfer personal data from the EEA to other jurisdictions. Recent legal developments in Europe have created complexity and uncertainty regarding transfers of personal data from the EEA to the United States. For example, on July 16, 2020, the Court of Justice of the European Union, or CJEU, invalidated the EU-US Privacy Shield Framework, or Privacy Shield, under which personal data could previously be transferred from the EEA to United States entities who had self-certified under the Privacy Shield scheme. The CJEU decision also created additional obligations and uncertainty around the ability to use standard contractual clauses for such data transfers. As government authorities issue further guidance on personal data export mechanisms or start aggressively taking enforcement action based on such guidance or the CJEU decision, we could suffer additional costs, complaints, and/or regulatory investigations or fines. If we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and adversely affect our financial results. These international laws and regulations may apply not only to us, but also to vendors that store or otherwise process personal data on our behalf, such as information technology vendors. If our data privacy and/or security measures fail to comply with European Union and United Kingdom data privacy laws, or if a vendor misuses data we have provided to it or fails to safeguard such data, we may be subject to litigation, regulatory investigations, enforcement notices, and/or enforcement actions imposing fines and/or requiring us to change the way we use personal data, as well as negative publicity, reputational harm, and a potential loss of business.

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

If we fail to keep apprised of and comply with applicable international, federal, state, or local regulatory requirements, we could be subject to a range of regulatory actions that could affect our or any collaborators' ability to seek to commercialize our clinical candidates. Any threatened or actual government enforcement action or litigation where private rights of action are available could also generate adverse publicity, damage our reputation, result in liabilities, fines and loss of business, and require that we devote substantial resources that could otherwise be used in other aspects of our business.

Risks Related to Commercialization of Our Product Candidates

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

The biotechnology and pharmaceutical industries are highly competitive and subject to significant and rapid technological change. Our success is highly dependent on our ability to discover, develop and obtain marketing approval for new and innovative products on a cost-effective basis and to market them successfully. In doing so, we face and will continue to face intense competition from a variety of businesses, including large pharmaceutical and biotechnology companies, academic institutions, government agencies and other public and private research organizations. These organizations may have significantly greater resources than we do and conduct similar research, seek patent protection and establish collaborative arrangements for research, development, manufacturing, and marketing of products that compete with our product candidates. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries.

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

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

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

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

Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. See the subsection titled “Business—Competition” in our 2020 Form 10-K.

Estimates of market opportunity and forecasts of market growth may prove to be smaller than we believe, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all.

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

In particular, certain of our product candidates are intended to address cancer, and, in particular, B cell malignancies. Cancer therapies are sometimes characterized as first line, second line, or third line, and the FDA often approves new therapies initially only for a particular line of use. When cancer is detected early enough, first line therapy is sometimes adequate to cure the cancer or prolong life without a cure. Whenever first line therapy, usually chemotherapy, antibody drugs, tumor-targeted small molecules, hormone therapy, radiation therapy, surgery, or a combination of these, proves unsuccessful, second line therapy may be administered. Second line therapies often consist of more chemotherapy, radiation, antibody drugs, tumor-targeted small molecules, or a combination of these. Third line therapies can include chemotherapy, antibody drugs and small molecule tumor-targeted therapies, more invasive forms of surgery and new technologies. The use of CAR T therapies has been limited to the relapsed/refractory patient subset. Our projections of both the number of people who have the cancers we are targeting, as well as the subset of people with these cancers in a position to receive a particular line of therapy and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. Consequently, even if our product candidates are approved for a later line of therapy, the number of patients that may be eligible for treatment with our product candidates may turn out to be much lower than expected.

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

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

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

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

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

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

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

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

Risks Related to Our Dependence on Third Parties

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

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

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

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

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

Pharmaceutical manufacturers are required to register their facilities and products manufactured at the time of submission of the marketing application and then annually thereafter with the FDA and certain state and foreign agencies. If the FDA or a comparable foreign regulatory authority does not approve our proposed contract manufacturer's facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for, or market our product candidates, if approved. Any discovery of problems with a product, or a manufacturing or laboratory facility used by us or our strategic partners, may result in restrictions on the product or on the manufacturing or laboratory facility, including marketed product recall, suspension of manufacturing, product seizure, or a voluntary withdrawal of the drug from the market. We may have little to no control regarding the occurrence of third-party manufacturer incidents.

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

Pharmaceutical manufacturers are also subject to extensive post-marketing oversight by the FDA and comparable regulatory authorities in the jurisdictions where the product is marketed, which include periodic unannounced and announced inspections by the FDA to assess compliance with cGMP requirements. If an FDA inspection of a manufacturer's facilities reveals conditions that the FDA determines not to comply with applicable regulatory requirements, the FDA may issue observations through a Notice of Inspectional Observations, commonly referred to as a "Form FDA 483" report. If observations in the Form FDA 483 report are not addressed in a timely manner and to the FDA's satisfaction, the FDA may issue a Warning Letter or proceed directly to other forms of enforcement action. Any failure by one of our contract manufacturers to comply with cGMP or to provide adequate and timely corrective actions in response to deficiencies identified in a regulatory inspection could result in further enforcement action that could lead to a shortage of products and harm our business, including withdrawal of approvals previously granted, seizure, injunction or

other civil or criminal penalties. The failure of a manufacturer to address any concerns raised by the FDA or foreign regulators could also lead to plant shutdown or the delay or withholding of product approval by the FDA in additional indications, or by foreign regulators in any indication. Certain countries may impose additional requirements on the manufacturing of drug products or drug substances, and on manufacturers, as part of the regulatory approval process for products in such countries. The failure by our third-party manufacturers to satisfy such requirements could impact our ability to obtain or maintain approval of our products in such countries.

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

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

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

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

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

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

Further, these investigators and CROs are not our employees and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to our product candidates and clinical trials. If independent investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of any product candidates that we develop. In addition, the use of third-party service providers may require us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. Additionally, disruptions caused by the COVID-19 pandemic may increase the likelihood that our CROs encounter difficulties or delays in initiating, enrolling, conducting, or completing our planned clinical trials. In particular, as a result of the pandemic, we have experienced and may continue to experience difficulty in accessing animal models, specifically non-human primate models, for the preclinical evaluation of our product candidates. Delays caused by the inability to access these models may cause our development timelines to be extended beyond what we anticipate.

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

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

In addition, clinical investigators may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the preclinical study or clinical trial, the integrity of the data generated at the applicable preclinical study or clinical trial site may be questioned and the utility of the preclinical study or clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA. Any such delay or rejection could prevent us from commercializing our clinical-stage product candidate or any future product candidates.

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

Our product development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. Therefore, for some of our product candidates, we may decide to enter into collaborations with pharmaceutical or biopharmaceutical companies for the development and potential commercialization of those product candidates.

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

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

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

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

Risks Related to Intellectual Property and Information Technology

We depend on intellectual property licensed from third parties and if we breach our obligations under these agreements or if any of these agreements is terminated, we may be required to pay damages, lose our rights to such intellectual property and technology, or both, which would harm our business.

We are dependent on patents, know-how, and proprietary technology, both our own and licensed from others. We are a party to a number of intellectual property license agreements and acquisition agreements pursuant to which we have acquired our core intellectual property rights. In the future, we expect to enter into additional license agreements. For example, with respect to our *ex vivo* cell engineering platform relying on hypoimmune technology, we have licensed certain intellectual property from Harvard, UCSF, and Washington University. Additionally, we acquired our *in vivo* cell engineering platform, which is based on fusogen technology, from Cobalt, which included several license agreements and options-to-license, as well as our glial progenitor cell and cardiomyocyte programs from Oscine and Cytocardia, respectively, both of which came with in-licenses. These license and acquisition agreements impose, and we expect that future license and acquisition agreements will impose, various diligence, milestone payment, royalty and other obligations on us. If we fail to comply with our obligations under these agreements, we may be required to pay damages and the licensor may have the right to terminate the license. Any termination of these licenses could result in the loss of significant rights and could harm our ability to develop or advance one of our cell engineering platforms, or develop, manufacture and/or commercialize one of our product candidates. See the subsection titled "Business— Key Intellectual Property Agreements" in Part I, Item 1, of our 2020 Form 10-K for additional information regarding these key agreements.

In addition, the agreements under which we license intellectual property or technology to or from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. Our business also would suffer if any current or future licensors fail to abide by the terms of the license, if the licensors fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights.

In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability.

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 research programs or product candidates and our business, financial condition, results of operations and prospects could suffer.

Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including those relating to:

- 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 license agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- whether we are complying with our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- the priority of invention of patented technology;
- the amount and timing of payments owed under license agreements; and
- the allocation of ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and by us and our partners.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. We are generally also subject to all of the same risks with respect to protection of intellectual property that we license as we are for intellectual property that we own, which are described below. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize our products could suffer.

We depend, in part, on our licensors to file, prosecute, maintain, defend, and enforce certain patents and patent applications that are material to our business.

Certain patents relating to our product candidates are owned or controlled by certain of our licensors. Each of our licensors generally has rights to file, prosecute, maintain, and defend the patents we have licensed from such licensor in their name, generally with our right to comment on such filing, prosecution, maintenance, and defense, with some obligation for the licensor to consider or incorporate our comments, for our exclusively licensed patents. We generally have the first right to enforce our exclusively licensed patent rights against third parties, although our ability to settle such claims often requires the consent of the licensor. If our licensors or any future licensees having rights to file, prosecute, maintain, and defend our patent rights fail to conduct these activities for patents or patent applications covering any of our product candidates, including due to the impact of the COVID-19 pandemic on our licensors' business operations, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using, or selling competing products. We cannot be certain that such activities by our

licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. Pursuant to the terms of the license agreements with some of our licensors, the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents and, even if we are permitted to pursue such enforcement or defense, we cannot ensure the cooperation of our licensors. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business. In addition, even when we have the right to control patent prosecution of licensed patents and patent applications, enforcement of licensed patents, or defense of claims asserting the invalidity of those patents, we may still be adversely affected or prejudiced by actions or inactions of our licensors and their counsel that took place prior to or after our assuming control. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our licensing partners.

Given the breadth of the application of our cell engineering platforms, in order to increase our ability to exploit our technologies, we may enter into collaborations and/or strategic partnerships in the future, and we may not realize the anticipated benefits of such collaborations or partnerships.

Research and development collaborations and strategic partnerships are prevalent in the biotechnology industry. The breadth of the application of our *in vivo* and *ex vivo* cell engineering platforms are attractive technologies for potential collaborations. These transactions are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration, and may not commit sufficient efforts and resources, or may misapply those efforts and resources;
- collaborators may not pursue development and commercialization of collaboration product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results or changes in their strategic focus;
- collaborators may delay, provide insufficient resources to, or modify or stop clinical trials for collaboration product candidates;
- collaborators could develop or acquire products outside of the collaboration that compete directly or indirectly with our products or product candidates;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital and personnel to pursue further development or commercialization of the applicable product candidates; and
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we may not have the exclusive right to commercialize such intellectual property.

The development and potential commercialization of our product candidates will require substantial additional capital to fund expenses. We may form or seek further strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop, including in territories outside the United States or for certain indications. These transactions can 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, product 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. As a result, if we enter into acquisition or in-license agreements or strategic collaborations, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, or if there are materially adverse impacts on our or the counterparty's operations resulting from COVID-19, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction or such other benefits that led us to enter into the arrangement.

In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. We may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. If and when we collaborate with a third-party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third-party. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of our technologies, product candidates and market opportunities. The collaborator may also consider alternative product 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 product candidate. We may also be restricted under any license agreements from entering into agreements on certain terms or at all with potential collaborators.

As a result of these risks, we may not be able to realize the benefit of our existing collaborations or any future collaborations or licensing agreements we may enter into. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators and changes to the strategies of the combined company. As a result, we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of such product candidate, reduce or delay one or more of our other development programs, delay the potential commercialization or reduce the scope of any planned sales or marketing activities for such product candidate, or increase our expenditures and undertake development, manufacturing or commercialization activities at our own expense. If we elect to increase our expenditures to fund development, manufacturing or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Our product candidates may also require specific components to work effectively and efficiently, and rights to those components may be held by others. We may be unable to in-license any compositions, methods of use, processes or other third party intellectual property rights from third parties that we identify. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, which would harm our business. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. Any delays in entering into new collaborations or strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies, which could harm our business prospects, financial condition, and results of operations.

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

We may not be successful in obtaining or maintaining necessary rights to product components and processes for our product development pipeline which may cause us to operate our business in a more costly or otherwise adverse manner that was not anticipated.

We own or license from third parties certain intellectual property rights necessary to develop our product candidates. The growth of our business will likely depend in part on our ability to acquire or in-license additional proprietary rights, including to advance our research or allow commercialization of our product candidates. In that event, we may be required to expend considerable time and resources to develop or license replacement technology. For example, our programs may involve additional technologies or product candidates that may require the use of additional proprietary rights held by third parties. Furthermore, other pharmaceutical companies and academic institutions may also have filed or are planning to file patent applications potentially relevant to our business. Our product candidates may also require specific formulations or other technology to work effectively and efficiently. These formulations or technology may be covered by intellectual property rights held by others. From time to time, in order to avoid infringing these third-party patents, we may be required to license technology from additional third parties to further develop or commercialize our product candidates. We may be unable to acquire or in-license any relevant third-party intellectual property rights, including any such intellectual property rights required to manufacture, use or sell our product candidates, that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, and as a result we may be unable to develop or commercialize the affected product candidates, which would harm our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may

need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license under such intellectual property rights, any such license may be non-exclusive, which may allow our competitors' access to the same technologies licensed to us.

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

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

We may be dependent on intellectual property licensed or sublicensed to us from, or for which development was funded or otherwise assisted by, government agencies, such as the National Institutes of Health, for development of our technology and product candidates.

Government agencies have provided and may in the future provide funding, facilities, personnel or other assistance in connection with the development of the intellectual property rights owned by or licensed to us. Such government agencies may have retained rights in such intellectual property, including the right to grant or require us to grant mandatory licenses or sublicenses to such intellectual property to third parties under certain specified circumstances, including if it is necessary to meet health and safety needs that we are not reasonably satisfying or if it is necessary to meet requirements for public use specified by federal regulations, or to manufacture products in the United States. Any exercise of such rights, including with respect to any such required sublicense of these licenses could result in the loss of significant rights and could harm our ability to commercialize or continue commercializing licensed products. For example, at least one of our in-licensed patent cases related to each of our ex vivo cell engineering and in vivo cell engineering platforms has been funded at least in part by the U.S. government. As a result, these patent cases are subject to certain federal regulations pursuant to the Bayh-Dole Act of 1980 (Bayh-Dole Act). In particular, the federal government retains a "nonexclusive, nontransferable, irrevocable, paid-up license" for its own benefit to inventions produced with its financial assistance. 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. Intellectual property discovered under government-funded programs are also subject to certain reporting requirements, compliance with which may require us or our licensors to expend substantial resources and failure to comply may lead to loss of rights. Such intellectual property is also subject to a preference for U.S. industry, which may limit our ability to contract with foreign product manufacturers for products covered by such intellectual property. Moreover, we sometimes collaborate with academic institutions to accelerate our preclinical research or development, and 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 unable to obtain and maintain sufficient intellectual property protection for our platform technologies and product 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 products may be adversely affected.

We anticipate that we will file additional patent applications both in the United States and in other countries, as appropriate. However, we cannot predict:

- if and when any patents will issue;
- the degree and range of protection any issued patents will afford us against competitors, including whether third parties will find ways to invalidate or otherwise circumvent our patents;

- whether others will apply for or 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 defend our patent rights, which may be costly whether we win or lose; or
- whether the patent applications that we own, or in-license will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our platform technologies and product candidates. 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.

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 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 products such as *in vivo* and *ex vivo* cell engineering product 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, however, that the claims in our pending patent applications covering the composition of matter of our product candidates will be considered patentable by the USPTO, or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered valid and enforceable by courts in the United States or foreign countries. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products "off-label" for those uses that are covered by our method of use patents. 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 strength of patents in the biotechnology and pharmaceutical field can be uncertain, and evaluating the scope of such patents involves complex legal, factual and scientific analyses 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. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries. Even if the patents do successfully issue, third parties may challenge the validity, enforceability, or scope thereof, which may result in such patents being narrowed, invalidated, or held unenforceable. 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. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing their products to avoid being covered by our claims. If the breadth or strength of protection provided by the patent applications we hold with respect to our product candidates is threatened, this could dissuade companies from collaborating with us to develop, and could threaten our ability to commercialize, our product candidates. 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. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced.

We 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 products.

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 product candidates in any jurisdiction. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third-party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or

abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

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. Further, we may not be aware of all third-party intellectual property rights potentially relating to our product 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. Because patent applications in the United States and most other countries are confidential for typically a period of 18 months after filing, or may not be published at all, we cannot be certain that we were the first to file any patent application related to our product candidates. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Furthermore, for U.S. applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. For U.S. applications containing a claim not entitled to priority before March 16, 2013, there is a greater level of uncertainty in the patent law in view of the passage of the America Invents Act, which brought into effect significant changes to the U.S. patent laws, including new procedures for challenging pending patent applications and issued patents.

Our patents or pending patent applications may be challenged in the courts or patent offices in the United States and abroad. For example, we may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in post-grant review procedures, oppositions, derivations, reexaminations, or *inter partes* review 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 product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Any failure to obtain or maintain patent protection with respect to our product candidates could have a material adverse effect on our business, financial condition, results of operations and prospects.

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 product candidates that are similar to ours but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patent or 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 our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- 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-license will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries;

- 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 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 in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent 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 patents and patent applications.

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

Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of trade secrets and other proprietary information.

In addition to the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce, and any other elements of our product candidates, technology and product discovery and development processes that involve proprietary know-how, information, or technology that is not covered by patents. 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 product 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 confidential information, however, may be difficult to protect. We seek to protect our trade secrets, know-how and confidential information, including our proprietary processes, in part, by entering into confidentiality agreements with our employees, consultants, outside scientific advisors, contractors, and collaborators. 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. 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. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, outside scientific advisors, contractors, and collaborators might intentionally or inadvertently disclose our trade secret information to competitors. In addition, competitors may 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. 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. 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, or misappropriation of our intellectual property by third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results, and financial condition.

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

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation, *inter partes* review, post-grant review and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. Furthermore, patent reform and changes to patent laws add uncertainty to the possibility of challenge to our

patents in the future. We cannot assure you that our product candidates and other proprietary technologies we may develop will not infringe existing or future patents owned by third parties. 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. 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.

Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are developing our product candidates. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current product candidates or future products, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Third parties may assert that we infringe their patents or other intellectual property, or that we are otherwise employing their proprietary technology without authorization, and may sue us. There may be third-party patents of which we are currently unaware with claims to compositions, formulations, methods of manufacture, or methods of use or treatment that cover our product 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 product candidates and other proprietary technologies we may develop, could be found to be infringed by our product candidate. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, 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 obtain patents in the future that may prevent, limit or otherwise interfere with our ability to make, use and sell our product candidates, and may claim that use of our technologies or the manufacture, use, or sale of our product candidates infringes upon these patents. If any such third-party patents were held by a court of competent jurisdiction to cover our technologies or product candidates, or if we are found to otherwise infringe a third-party's intellectual property rights, the holders of any such patents may be able to block, including by court order, our ability to develop, manufacture or commercialize the applicable product candidate unless we obtain a license under the applicable patents or other intellectual property, or until such patents expire or are finally determined to be held invalid or unenforceable. Such a license may not be available 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. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business.

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 product 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. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

Third parties asserting their patent or other intellectual property rights against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates or force us to cease some of our business operations. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, cause development delays, and may impact our reputation. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties, or redesign our infringing products, which may be impossible on a cost-effective basis or require substantial time and monetary expenditure. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

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

If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim we infringe their patents or that the patent covering our product candidate is invalid or unenforceable, or both. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent, including lack of novelty, obviousness, non-enablement or insufficient written description or that that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, *inter partes* review, post-grant review, and equivalent proceedings in foreign jurisdictions, such as opposition or derivation proceedings. Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover and protect our product candidates. 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 patented technology falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1). With respect to the validity of our patents, for example, we cannot be certain that there is no invalidating prior art of which we, our patent counsel, and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates and such an outcome may 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. Such a loss of patent protection could have a material adverse impact on our business. 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.

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

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. Although 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. Noncompliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. In any such event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

The lives of our patents may not be sufficient to effectively protect our products and business.

Patents have a limited lifespan. In the United States, if all maintenance fees are paid timely, the natural expiration of a patent is generally 20 years after its first effective nonprovisional filing date. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such product candidates are commercialized. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from biosimilar or generic medications. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours. Our patents issued as of October 30, 2020 will expire on dates ranging from 2023 to 2037, subject to any patent extensions that may be available for such patents. If patents are issued on our patent applications pending as of October 30, 2020, the resulting patents are projected to expire on dates ranging from 2023 to 2041. In addition, although upon issuance in the United States a patent's life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. A patent term extension 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 patent term extension does not extend to the full scope of the claim, but instead only to the scope of the product as approved. Laws governing analogous patent term extensions 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 patent term extension 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 product 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 we do not have sufficient patent life to protect our products, our business and results of operations will be adversely affected.

We may be 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 product candidates or as a result of questions regarding co-ownership of potential joint inventions. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship. 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.

We or our licensors may have relied on third-party consultants or collaborators or on funds from third parties, such as the U.S. government, such that we or 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 patents, including 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.

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

Moreover, any name we have proposed to use with our product 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.

Our internal computer systems, or those used by our third-party research institution collaborators, CROs, CDMOs, or other contractors or consultants, may fail or suffer security breaches.

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit confidential information (including but not limited to intellectual property, proprietary business information and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have outsourced elements of our operations to third parties, and as a result we manage a number of third-party contractors who have access to our confidential information, including third party vendors of IT and data security systems and services. While we generally have agreements requiring such vendors to use industry standard practices for data security, we have no operational control over them.

Despite the implementation of security measures (including edge technology designed to identify and protect our network from infiltration by third party systems), our internal computer systems and those of our future CROs and CDMOs, and other contractors and consultants as well as third party vendors of IT and data security systems and services, are vulnerable to damage and interruptions from security breaches, computer viruses, fraud and similar incidents involving the loss or unauthorized access of confidential information. One such third party vendor is SolarWinds Corporation (SolarWinds), a provider of IT monitoring and management products and services, including its Orion Platform products, which are used by over 30,000 businesses including ours. SolarWinds experienced a cyberattack that appears likely to be the result of a supply chain attack by an outside nation state. SolarWinds has stated that, as a result of the attack, software updates related to its Orion Platform products delivered between March and June 2020 included vulnerabilities, and that its investigation is ongoing. Since being notified of the attack, we have taken steps to mitigate the vulnerabilities identified within the Orion Platform products. Although investigations remain ongoing regarding the extent to which our confidential information was accessed, lost or stolen as a result of this cyberattack on SolarWinds, any such access, loss or theft could have a materially adverse effect on our business.

While we have not to our knowledge experienced any material system failure, accident or security breach to date, because techniques used to obtain unauthorized access or to sabotage systems are constantly evolving, change frequently, and generally are not recognized until they are launched against a target, we cannot be sure that our continued data protection efforts and investment in information technology will prevent future significant breakdowns, data leakages, breaches in our systems or the systems of our third party contractors and collaborators, or other cyber incidents that could have a material adverse effect upon our reputation, business, operations or financial condition. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs and the development of our product candidates could be delayed. For example, the loss of or inability to access clinical trial data for our product candidates could result in delays in further development and commercialization of our product candidates and in our regulatory and marketing approval efforts and significantly increase our costs to recover or reproduce the data. Furthermore, significant disruptions or security breaches of our internal information technology systems or our third party contractors and collaborators' information technology systems could result in the loss, misappropriation, and/or unauthorized access, use, or disclosure of, or the prevention of access to, our confidential information (including trade secrets or other intellectual property, proprietary business information, and personal information), which could also result in financial, legal, business, and reputational harm to us. Any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our clinical trial subjects or employees, could delay further development and commercialization of our product candidates, harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

We have and will enter into collaboration, license, contract research and/or manufacturing relationships with contract organizations that operate in certain countries that are at heightened risk of theft of technology, data and intellectual property through direct intrusion by private parties or foreign actors, including those affiliated with or controlled by state actors. Accordingly, our efforts to protect and 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, and we may be at heightened risk of losing our proprietary intellectual property rights around the world, including outside of such countries, to the extent such theft or intrusion destroy the proprietary nature of our intellectual property.

Risks Related to Ownership of Our Common Stock

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

As of March 31, 2021, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates owned approximately 36.2% of our outstanding voting stock. Therefore, these stockholders will have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

Future sales of our common stock in the public market could cause our common stock price to fall.

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

As of March 31, 2021, 187.6 million shares of common stock were outstanding.

Substantially all shares of common stock sold in our IPO (excluding any shares sold to our directors or officers in the directed share program) are freely tradable without restriction or further registration under the Securities Act unless held by our "affiliates" as defined in Rule 144 under the Securities Act. The resale of the remaining 160.4 million shares, or 85.5% of our outstanding shares of common stock as of March 31, 2021, is currently prohibited or otherwise restricted as a result of securities law provisions, market standoff agreements entered into by certain of our stockholders with us or lock-up agreements entered into by our stockholders with the underwriters in connection with our initial public offering. However, subject to applicable securities law restrictions, these shares will be able to be sold in the public market beginning on August 3, 2021. Shares issued upon the exercise of stock options outstanding under our equity incentive plans or pursuant to future awards granted under those plans will become available for sale in the public market to the extent permitted by the provisions of applicable vesting schedules, market stand-off agreements and/or lock-up agreements, as well as Rules 144 and 701 under the Securities Act.

As of March 31, 2021, the holders of approximately 134.1 million shares, or 71.5% of our outstanding shares, of our common stock will have rights, subject to some conditions, to require us to file registration statements covering the sale of their shares or to include their shares in registration statements that we may file for ourselves or our other stockholders. We also registered the offer and sale of all shares of common stock that we may issue under our equity compensation plans. Once we register the offer and sale of shares for the holders of registration rights and shares that may be issued under our equity incentive plans, these shares will be able to be sold in the public market upon issuance, subject to the lock-up agreements.

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

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

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

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

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

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

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

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

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

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the sole and exclusive forum, to the fullest extent permitted by law, for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a breach of a fiduciary duty owed by any director, officer or other employee to us or our stockholders, (iii) any action asserting a claim against us or any director, officer, or other employee arising pursuant to the Delaware General Corporation Law, (iv) any action to interpret, apply, enforce, or determine the validity of our second amended and restated certificate of incorporation or amended and restated bylaws, or (v) any other action asserting a claim that is governed by the internal affairs doctrine, shall be the Court of Chancery of the State of Delaware (or another state court or the federal court located within the State of Delaware if the Court of Chancery does not have or declines to accept jurisdiction), in all cases subject to the court's having jurisdiction over indispensable parties named as defendants. In addition, our amended and restated certificate of incorporation provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act but that the forum selection provision will not apply to claims brought to enforce a duty or liability created by the Exchange Act.

Although we believe these provisions benefit us by providing increased consistency in the application of Delaware law for the specified types of actions and proceedings, the provisions may have the effect of discouraging lawsuits against us or our directors and officers. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, financial condition, and operating results. For example, under the Securities Act, federal courts have concurrent jurisdiction over all suits brought to enforce any duty or liability created by the Securities Act, and investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Any person or entity purchasing or otherwise acquiring any interest in our shares of capital stock shall be deemed to have notice of and consented to this exclusive forum provision, but will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

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

Under the Tax Cuts and Jobs Act of 2017, as modified by the Coronavirus Aid, Relief, and Economic Stability Act, or CARES Act, our federal net operating losses, or NOLs, generated in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal NOLs in tax years beginning after December 31, 2020, is limited to 80% of taxable

income. It is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act of 2017, or the CARES Act. In addition. under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards, or NOLs, and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income or taxes may be limited. We may have experienced ownership changes in the past and may experience ownership changes as a result of subsequent shifts in our stock ownership (some of which are outside our control). As a result, our ability to use our pre-change NOLs and tax credits to offset post-change taxable income, if any, could be subject to limitations. Similar provisions of state tax law may also apply. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For example, California recently imposed limits on the usability of California state NOLs and tax credits to offset California taxable income in tax years beginning after 2019 and before 2023. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and tax credits.

General Risk Factors

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

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

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

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

Our corporate headquarters and other facilities are located in areas that have experienced significant natural disasters, including the San Francisco Bay Area and Seattle, Washington, which has experienced severe effects from wildfires and, in the case of San Francisco, severe earthquakes. We do not carry earthquake insurance. Earthquakes, wildfires or other natural disasters could severely disrupt our operations, and could materially and adversely affect 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 or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

Furthermore, integral parties in our supply chain are similarly vulnerable to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our business.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. 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 recipients in the public or private sector. We may engage third parties to sell our products 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.

The withdrawal of the United Kingdom from the European Union, commonly referred to as "Brexit," may adversely impact our ability to obtain regulatory approvals of our product candidates in the European Union, result in restrictions or imposition of taxes and duties for importing our product candidates into the European Union, and may require us to incur additional expenses in order to develop, manufacture and commercialize our product candidates in the European Union.

Following the result of a referendum in 2016, the United Kingdom left the European Union on January 31, 2020, commonly referred to as "Brexit." Pursuant to the formal withdrawal arrangements agreed between the United Kingdom and the European Union, the United Kingdom will be subject to a transition period until December 31, 2020 (the Transition Period), during which EU rules will continue to apply. Negotiations between the United Kingdom and the European Union are expected to continue in relation to the customs and trading relationship between the United Kingdom and the European Union following the expiry of the Transition Period.

Since a significant proportion of the regulatory framework in the United Kingdom applicable to our business and our product candidates is derived from EU directives and regulations, Brexit, following the Transition Period, could materially impact the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the United Kingdom or the European Union. For example, as a result of the uncertainty surrounding Brexit, the EMA relocated to Amsterdam from London. Following the Transition Period, the United Kingdom will no longer be covered by the centralized procedures for obtaining EU-wide marketing authorization from the EMA and, unless a specific agreement is entered into, a separate process for authorization of drug products, including our product candidates, will be required in the United Kingdom, the potential process for which is currently unclear. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the United Kingdom or the European Union and restrict our ability to generate revenue and achieve and sustain profitability. In addition, we may be required to pay taxes or duties or be subjected to other hurdles in connection with the importation of our product candidates into the European Union, or we may incur expenses in establishing a manufacturing facility in the European Union in order to circumvent such hurdles. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom or the European Union for our product candidates, or incur significant additional expenses to operate our business, which could significantly and materially harm or delay our ability to generate revenues or achieve profitability of our business. Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the United Kingdom.

From the beginning of 2021 (when the transitional period following the United Kingdom's withdrawal from the European Union expires), we have to comply with the GDPR as well as the UK GDPR. Each regime has the ability to fine us up to the greater of €20 million (£17.5 million) or 4% of global turnover for non-compliance. The relationship between the UK and the EU in relation to transfers of personal data from the EU to the UK is not fully settled by the Brexit Trade and Cooperation Agreement (TCA). Instead, the TCA establishes a four- to six-month grace period during which transfers of personal data from the EU to the UK can continue without additional safeguards, provided that the UK maintains its pre-TCA data protection laws. During this time, the European Commission may adopt a UK adequacy decision which organizations can then rely on for EU to UK personal data transfers but, if no UK adequacy decision is adopted, the UK will be considered a third country at the end of the grace period and we will be required to implement additional safeguards for personal data transfers—some of which are subject currently being scrutinized or challenged—which could lead to additional costs and increase our overall risk exposure.

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

Even if the FDA or any comparable foreign regulatory authority approves the marketing of any product candidates that we develop, physicians, healthcare providers, patients, or the medical community may not accept or use them. Additionally, the product candidates that we are developing are based on our proprietary platforms, which are new technologies. If these products do not

achieve an adequate level of acceptance, we may not generate significant product revenues or any profits from operations. The degree of market acceptance of any of our product candidates will depend on a variety of factors, including:

- the timing of market introduction;
- the terms of any approvals and the countries in which approvals are obtained;
- the number and clinical profile of competing products;
- our ability to provide acceptable evidence of safety and efficacy;
- the prevalence and severity of any side effects;
- relative convenience and ease of administration;
- cost-effectiveness;
- patient diagnostics and screening infrastructure in each market;
- marketing and distribution support;
- adverse publicity about our product candidates;
- availability of coverage, adequate reimbursement and sufficient payment from health maintenance organizations and other insurers, both public and private, for our product candidates, or the procedures utilizing our product candidates, if approved;
- the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors and government authorities; and
- other potential advantages over alternative treatment methods.

In addition, although we are not utilizing replication competent vectors, adverse publicity due to the ethical and social controversies surrounding the therapeutic use of such technology, and reported side effects from any clinical trials using these technologies or the failure of such trials to demonstrate that these therapies are safe and effective may limit market acceptance of our product candidates. If our product candidates are approved but fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers or others in the medical community, we will not be able to generate significant revenue.

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

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

Patents are of national or regional effect, and filing, prosecuting, maintaining and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can have a different scope and strength than do those in the United States. In addition, the laws of some foreign countries, particularly certain developing 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 rights are not as strong as those in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or adequate to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to biopharmaceutical products, which could make it difficult in those jurisdictions for us to stop the infringement or misappropriation of our patents or other intellectual property rights, or the marketing of competing products in violation of our proprietary rights. Proceedings to enforce our patent and other intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Furthermore, such proceedings could put our patents at risk of being invalidated, held unenforceable, or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims of infringement or misappropriation against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Similarly, if our trade secrets are disclosed in a foreign jurisdiction, competitors worldwide

could have access to our proprietary information and we may be without satisfactory recourse. Such disclosure could have a material adverse effect on our business. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. In addition, certain developing countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third-party, which could materially diminish the value of those patents. In addition, many countries limit the enforceability of patents against government agencies or government contractors. This could limit our potential revenue opportunities. 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.

Because of the expense and uncertainty of litigation, we may conclude that even if a third-party is infringing our issued patents, 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, which typically last for years before they are concluded, 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 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 and 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 product candidates, or enter into development partnerships that would help us bring our product candidates to market.

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

Competitors may infringe our patents or other intellectual property or the intellectual property of our licensors. To cease such infringement or unauthorized use, we may be required to file patent 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. In addition, in an infringement proceeding or a declaratory judgment action, a court may decide that one or more of our patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceeding could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

Interference or derivation proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to, or the correct inventorship of, our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation, interference, derivation or other proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees.

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 this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry 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 owned and licensed patents. Recent patent reform legislation in the United States and other countries, including the Leahy-Smith

America Invents Act, or the 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 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 post-grant review, *inter partes* review, and derivation proceedings. 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 product 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 issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on decisions by Congress, the federal courts, 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 or to enforce our existing 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 naturally-occurring substances are not patentable. Although we do not believe that any of the patents owned or licensed by us will be found invalid based on this decision, we cannot predict how future decisions by Congress, the federal courts or the USPTO may impact the value of our patents.

We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties.

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers, or that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees. 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 product 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.

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

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

- the commencement, enrollment, or results of current and future preclinical studies and clinical trials and trials we may conduct, or changes in the development status of our product candidates;

- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including, without limitation, the issuance by the FDA of a "refusal to file" letter or a request for additional information;
- adverse results or delays in clinical trials;
- our decision to initiate a preclinical study or clinical trial, not to initiate a preclinical study or clinical trial or to terminate an existing preclinical study or clinical trial;
- adverse actions taken by regulatory agencies with respect to our preclinical studies or clinical trials, manufacturing supply chain or sales and marketing activities, including failure to receive regulatory approval of our product candidates;
- changes in laws or regulations, including, but not limited to, preclinical study or clinical trial requirements for approvals;
- any adverse changes to our relationship with manufacturers or suppliers;
- manufacturing, supply or distribution shortages;
- our failure to commercialize our product candidates;
- changes in the structure of healthcare payment systems;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- variations in our results of operations;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or *in vivo* and *ex vivo* cell engineering products in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- announcements made by us or our competitors about new product and service offerings, success or setbacks related to product or service offerings that exist or are under development, acquisitions, strategic relationships, joint ventures, or capital commitments;
- our inability to establish collaborations, if needed;
- our ability to effectively manage our growth;
- the size and growth of our initial target markets;
- changes in the market valuations of similar companies;
- press reports, whether or not true, about our business;
- sales or perceived potential sales of our common stock by us or our stockholders in the future;
- overall fluctuations in the equity markets;
- ineffectiveness of our internal controls;
- changes in accounting practices or principles;
- changes or developments in the global regulatory environment;
- litigation involving us, our industry or both, or investigations by regulators into our operations or those of our competitors;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. If the market price of our common stock does not exceed your purchase price, you may not realize any return on, and may lose some or all of, your investment.

Our quarterly 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:

- timing and variations in the level of expense related to the current or future development of our programs;
- timing and status of enrollment for our clinical trials;
- impacts from the COVID-19 pandemic on us or third parties with which we engage;
- results of clinical trials, or the addition or termination of clinical trials or funding support by us or potential future partners;
- our execution of any collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under potential future arrangements or the termination or modification of any such potential future arrangements;
- any intellectual property infringement, misappropriation or violation 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 product candidate we may develop receive regulatory approval, the timing and terms of such approval and market acceptance and demand for such product candidates;
- the timing and cost to establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly with current or future collaborators;
- regulatory developments affecting current or future product candidates or those of our competitors;
- the amount of expense or gain associated with the change in value of the success payments and contingent consideration; and
- changes in general market and economic conditions.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our 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.

We could be subject to securities class action litigation.

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

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

The trading market for our common stock will be influenced in part by the research and reports that securities or industry analysts may publish about us, our business, our market, or our competitors. If one or more of these analysts initiate research with an

unfavorable rating or downgrade our common stock, provide a more favorable recommendation about our competitors or publish inaccurate or unfavorable research about our business, our common stock price would likely decline. If any analyst who may cover us were to cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause the trading price or trading volume of our common stock to decline.

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

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

- not being required to have our independent registered public accounting firm audit our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act;
- reduced disclosure obligations regarding executive compensation in our periodic reports and annual report on Form 10-K; and
- exemptions from the requirements of holding non-binding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We could be an emerging growth company for up to five years following the completion of our initial public offering. Our status as an emerging growth company will end as soon as any of the following takes place:

- the last day of the fiscal year in which we have more than $1.07 billion in annual revenue;
- the date we qualify as a "large accelerated filer," with at least $700 million of equity securities held by non-affiliates;
- the date on which we have issued, in any three-year period, more than $1.0 billion in non-convertible debt securities; or
- the last day of the fiscal year ending after the fifth anniversary of the completion of our initial public offering, which is December 31, 2026.

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

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to use this extended transition period for any new or revised accounting standards during the period in which we remain an emerging growth company (or we affirmatively and irrevocably opt out of the extended transition period); however, we may adopt certain new or revised accounting standards early. As a result, these financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

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

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

In addition, changing laws, regulations, and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs, and making some activities more time consuming.

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

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

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

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

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

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

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

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

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

Recent Sales of Unregistered Securities

Unregistered securities sold by us from January 1, 2021 through March 31, 2021, for which share numbers have been adjusted to reflect the 1-for-4 reverse stock split which became effective on January 27, 2021, consisted of 73,289 shares of common stock issued upon the exercise of options for aggregate proceeds of approximately $0.1 million.

Use of Proceeds from our Initial Public Offering of Common Stock

On February 3, 2021, our Registration Statement on Form S-1 (File No. 333-252061) relating to our IPO of common stock was declared effective. On February 8, 2021, we closed our IPO and issued 27.0 million shares of common stock, including 3.5 million shares of common stock sold pursuant to the underwriters' full exercise of their option to purchase additional shares, at a public offering price of $25.00 per share, for aggregate net proceeds of $626.4 million. Morgan Stanley & Co. LLC, Goldman Sachs & Co. LLS, J.P. Morgan Securities LLC, and BofA Securities, Inc. acted as joint bookrunning managers of the IPO and as representatives of the underwriters. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning 10.0% or more of any class of our equity securities or to any other affiliates.

There has been no material change in the planned use of proceeds from the IPO from that described in the prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on February 3, 2021.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

(a)

Not applicable.

(b)

Not applicable.

Item 6. Exhibits

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation (incorporated herein by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-1 (File No. 333-252061), filed with the SEC on January 28, 2021).
3.2	Amended and Restated Bylaws (incorporated herein by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-1 (File No. 333-252061), filed with the SEC on January 28, 2021).
4.1	Reference is made to Exhibits 3.1 through 3.2
4.2	Form of Common Stock Certificate (incorporated herein by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-1 (File No. 333-252061), filed with the SEC on January 28, 2021).
10.24*	Third Amendment to Agreement and Plan of Merger dated March 22, 2021 by and between the registrant and Cobalt Biomedicine Inc.
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*+	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*+	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

\+ The certification attached as Exhibit 32.1 and Exhibit 32.2 that accompany this Quarterly Report on Form 10-Q is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

SIGNATURES

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

Company Name

Date: May 5, 2021

By: /s/ Steven D. Harr, M.D.
Steven D. Harr, M.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 5, 2021

By: /s/ Nathan Hardy
Nathan Hardy
Executive Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 10.24

THIRD AMENDMENT TO AGREEMENT AND PLAN OF MERGER

This Third Amendment ("Third Amendment"), dated as of March 22, 2021 (the "Third Amendment Effective Date"), to Agreement and Plan of Merger is entered into by and between Sana Biotechnology, Inc., a Delaware corporation ("Parent"), and VentureLabs VI, Inc., a Delaware corporation, solely in its capacity as the Stockholders' Representative ("Stockholders' Representative"), and amends that certain Agreement and Plan of Merger dated as of December 20, 2018 by and among Parent, Stockholders' Representative, Sana Biotechnology, IV, Inc., a Delaware corporation and a wholly owned subsidiary of Parent ("Merger Sub"), and Cobalt Biomedicine, Inc., a Delaware corporation (the "Company"), as amended by those certain amendments thereto dated as of January 29, 2019, and February 8, 2019 (the "Agreement").

RECITALS

WHEREAS, Parent, Merger Sub, the Company and Stockholders' Representative are parties to the Agreement.

WHEREAS, the Agreement includes terms for payment by Parent to Stockholders' Representative or its designee of a Milestone Payment payable upon achievement of a Qualifying Valuation Milestone, which Qualifying Valuation Milestone includes terms of calculation which differ depending on whether or not Parent has consummated a Parent IPO.

WHEREAS, as of the Third Amendment Effective Date, Parent has consummated the Parent IPO,and Parent's Common Stock commenced trading on a Trading Market on February 4, 2021.

WHEREAS, pursuant to Section 9.7 of the Agreement, the Agreement may be amended by aninstrument in writing signed by Parent and Stockholders' Representative.

WHEREAS, in light of the Parent IPO, Parent and Stockholder's Representative wish to clarify and amend the terms of calculation for the Qualifying Valuation Milestone in accordance with Section 9.7 of the Agreement.

AGREEMENT

NOW THEREFORE, in consideration of the respective covenants and promises contained hereinand for other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, the parties hereto agree as follows:

1. Defined Terms. Capitalized terms used but not defined herein shall have the meanings ascribed to them in the Agreement.

2. Amendments to Section 9.1 of the Agreement.

   a. The term "Qualifying Valuation Event" as set forth in Section 9.1 of the Agreement is hereby amended and restated in its entirety to read as follows:

      "Qualifying Valuation Event" means, at any time prior to the twentieth (20th) anniversary of the Closing Date, a Thirty Day Volume Weighted Average Market Capitalization of Parent equal to or greater than $8,120,768,120.

b. The term "QVM Valuation" as set forth in Section 9.1 of the Agreement is hereby amended and restated in its entirety to read as follows:

"QVM Valuation" means $2,706,922,707.

c. The term "Thirty Day Volume Weighted Average Market Capitalization" is added to Section 9.1 of the Agreement with the meaning as follows:

"Thirty Day Volume Weighted-Average Market Capitalization" means, with respect to any thirty (30) consecutive Trading Day period, the amount that is equal to (i) the product of (a) the Volume Weighted Average Price for such thirty (30) consecutive Trading Day period multiplied by (b) the total number of outstanding shares of Common Stock of the Parent as of the last day of the calendar month in which such thirty (30) consecutive Trading Day period ends (excluding any repurchases during that calendar month), as reported by Parent's transfer agent.

d. The term "Trading Day" is added to Section 9.1 of the Agreement with the meaning asfollows:

"Trading Day" means a day on which the principal Trading Market is open for trading.

e. All references to the term "trading day" in the Agreement are hereby replaced with the term "Trading Day."

f. The term "Trading Market" is added to Section 9.1 of the Agreement with the meaning asfollows:

"Trading Market" means the Nasdaq Global Select Market or any successors thereto, or,if not the Nasdaq Global Select Market or successor thereto, any other nationally recognized markets or exchanges on which the shares of Common Stock may become subsequently listed or quoted for trading on the date in question, which may include the NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market, or the New York Stock Exchange (or any successors to any of the foregoing).

3. Full Force and Effect; No Waiver of Rights. Except as expressly modified by this Third Amendment, the Agreement is unmodified and this Third Amendment shall not impair the full force andeffect of the Agreement and shall not constitute a waiver of any right held by any party under the Agreement.

4. General Provisions. The provisions of Article VII (Termination) and Sections 5.10 (Confidentiality; Public Announcements), 9.2 (Notices), 9.4 (References), 9.6 (Assignment), 9.7 (Amendment; Modification), 9.8 (Waiver), 9.9 (Severability), 9.10 (Burden and Benefit), 9.11 (GoverningLaw), 9.12 (Consent to Jurisdiction), 9.13 (Waiver of Trial by Jury), 9.14 (Specific Performance), 9.15 (Cumulative Rights), 9.16 (Expenses), 9.17 (Representation by Counsel) and 9.18 (Execution and Counterparts) of the Agreement shall apply mutatis mutandis to this Third Amendment.

IN WITNESS WHEREOF, the parties hereto have executed this Third Amendment or caused this ThirdAmendment to be duly executed on their respective behalf, by their respective officers thereunto duly authorized, all as of the day and year first above written.

SANA BIOTECHNOLOGY, INC.

By: /s/ Steven D. Harr, M.D.

Name: Steven D. Harr, MD

Title: Chief Executive Officer

VENTURELABS VI, INC.

By: /s/ Noubar Afeyan

Name:

Title:

[Signature Page to Third Amendment to Agreement and Plan of Merger]

Exhibit 31.1

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

I, Steven D. Harr, M.D., certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 5, 2021

By: /s/ Steven D. Harr, M.D.
Steven D. Harr, M.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Nathan Hardy, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 5, 2021

By: /s/ Nathan Hardy
Nathan Hardy
Executive Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Sana Biotechnology, Inc. (the "Company") on Form 10-Q for the period ending March 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: May 5, 2021

By: /s/ Steven D. Harr, M.D.
Steven D. Harr, M.D.
President and 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

In connection with the Quarterly Report of Sana Biotechnology, Inc. (the "Company") on Form 10-Q for the period ending March 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: May 5, 2021

By: /s/ Nathan Hardy
Nathan Hardy
Executive Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)