## UNITED STATES SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON, DC 20549** 

### **FORM 10-Q**

(Mark One)  ☑ QUARTERLY REPORT PURSUANT TO SECTION	ON 13 OR 15(d) OF THE SECURIT	TIES EXCHANGE ACT OF 1934	
	uarterly period ended September 3		
	OR		
☐ TRANSITION REPORT PURSUANT TO SECTION	ON 13 OR 15(d) OF THE SECURIT	ΓΙΕS EXCHANGE ACT OF 1934	
	r the transition period from to		
	ommission File Number: 001-39941		
Sana	Biotechnology,	Inc	
	me of Registrant as Specified in its		
<b>Delaware</b> (State or other jurisdiction of incorporation or organization)		83-1381173 (I.R.S. Employer Identification No.)	
	188 East Blaine Street, Suite 400 Seattle, Washington 98102 (Address of principal executive offices)		
Registrant's telep	phone 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 report 12 months (or for such shorter period that the registrant was require Yes ⊠ No □	•	,,	lin
Indicate by check mark whether the registrant has submitted electron ( $\S 232.405$ of this chapter) during the preceding 12 months (or for s			
Indicate by check mark whether the registrant is a large accelerated company. See the definitions of "large accelerated filer," "accelerate Act.			ge
Large accelerated filer $\ \square$		Accelerated filer	
Non-accelerated filer ⊠ Emerging growth company ⊠		Smaller reporting company	
- 8 8 8 5 · · · · · · · · · · · · · · · ·			
If an emerging growth company, indicate by check mark if the registinancial accounting standards provided pursuant to Section 13(a) of		ransition period for complying with any new or revised	
Indicate by check mark whether the registrant is a shell company (a	as defined in Rule 12b-2 of the Exchange	Act). Yes □ No ⊠	
As of November 5, 2021, the registrant had 188,832,954 shares of	f common stock, \$0.0001 par value per sh	are, outstanding.	

#### TABLE OF CONTENTS

		Page
PART I.	FINANCIAL INFORMATION	
Item 1.	Financial Statements (Unaudited)	5
	Condensed Consolidated Balance Sheets	5
	Condensed Consolidated Statements of Operations	6
	Condensed Consolidated Statements of Comprehensive Income (Loss)	7
	Condensed Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)	8
	Condensed Consolidated Statements of Cash Flows	9
	Notes to Unaudited Condensed Consolidated Financial Statements	10
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	22
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	33
Item 4.	Controls and Procedures	33
PART II.	OTHER INFORMATION	
Item 1.	<u>Legal Proceedings</u>	34
Item 1A.	Risk Factors	34
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	91
Item 3.	<u>Defaults Upon Senior Securities</u>	91
Item 4.	Mine Safety Disclosures	91
Item 5.	Other Information	91
Item 6.	<u>Exhibits</u>	92
	<u>Signatures</u>	93

#### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. 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, 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 with respect to 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 expectations, including the buildout of our manufacturing facility and capabilities and the timing thereof;
- 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 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)

		ember 30, 2021 (unaudited)	December 31, 2020		
ASSETS					
Current assets:					
Cash and cash equivalents	\$	433,670	\$	124,806	
Marketable securities		170,041		253,458	
Prepaid expenses and other current assets		9,134		6,203	
Total current assets		612,845		384,467	
Property and equipment, net		63,445		46,775	
Operating lease right-of-use assets		84,828		63,168	
Restricted cash		8,819		2,143	
Long-term marketable securities		262,401		33,731	
Intangible asset		59,195		59,195	
Goodwill		140,627		140,627	
Other non-current assets		591		190	
TOTAL ASSETS	\$	1,232,751	\$	730,296	
LIABILITIES, CONVERTIBLE PREFERRED STOCK, AND STOCKHOLDERS' EQUITY (DEFICIT)					
Current liabilities:	ď	2.047	ď	2.252	
Accounts payable	\$	3,947	\$	2,253	
Accrued compensation		20,218		16,020	
Accrued expenses and other current liabilities		12,884		9,466	
Operating lease liabilities		6,502		3,712	
Contingent consideration		43,459		-	
Success payment liabilities		5,000		21 451	
Total current liabilities		92,010		31,451	
Operating lease liabilities, net of current portion		92,403		68,197	
Contingent consideration, net of current portion		88,522		121,901	
Success payment liabilities, net of current portion		129,192		76,494	
Other non-current liabilities		539		540	
Total liabilities		402,666		298,583	
Commitments and contingencies (Note 10)  Convertible preferred stock, \$0.0001 par value; zero and 537,786 shares authorized as of September 30, 2021 and December 31, 2020, respectively; zero and 134,113 shares issued and outstanding as of September 30, 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 September 30, 2021 and December 31, 2020, respectively; zero shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively		-		-	
Common stock, \$0.0001 par value; 750,000 and 707,000 shares authorized as of September 30, 2021 and December 31, 2020, respectively; 182,908 and 16,170 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively		18		2	
Additional paid-in capital		1,504,778		8,216	
Accumulated other comprehensive income (loss)		(82)		30	
Accumulated deficit		(674,629)		(429,432)	
Total stockholders' equity (deficit)		830,085		(421,184)	
TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK, AND STOCKHOLDERS'		350,005		(121,104)	
EQUITY (DEFICIT)	\$	1,232,751	\$	730,296	

# Sana Biotechnology, Inc. Condensed Consolidated Statements of Operations (unaudited)

(in thousands, except per share amounts)

	Th	ree Months End	ded Sep	otember 30,	1	Nine Months End	ed Se	otember 30,
		2021		2020		2021		2020
Operating expenses:								
Research and development	\$	53,245	\$	40,056	\$	140,121	\$	96,453
Research and development related success payments and contingent								
consideration		16,753		4,489		67,778		57,309
General and administrative		13,433		7,099		37,731		19,063
Total operating expenses		83,431		51,644		245,630	'	172,825
Loss from operations		(83,431)		(51,644)		(245,630)		(172,825)
Interest income, net		158		148		409		622
Other income, net		10		44		24		68
Net loss	\$	(83,263)	\$	(51,452)	\$	(245,197)	\$	(172,135)
Net loss per common share - basic and diluted	\$	(0.46)	\$	(3.76)	\$	(1.53)	\$	(14.05)
Weighted-average number of common shares - basic and diluted		181,827		13,680		160,515		12,249

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

	 Three Months End	led September 30,	Nine Months E	nded September 30,
	2021	2020	2021	2020
Net loss	\$ (83,263)	(51,452)	(245,197)	(172,135)
Other comprehensive income (loss), net of tax:				
Unrealized gain (loss) on marketable securities, net	(95)	32	(112)	29
Total comprehensive loss	\$ (83,358)	\$ (51,420)	\$ (245,309)	\$ (172,106)

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

	Convertible Sto		eferred	Commo	on S	tock		Additional Paid-In		Accumulated Other omprehensive	Α	Accumulated	St	Total ockholders' Equity
	Shares		Amount	Shares		Amount		Capital	I	ncome (Loss)		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				27.025		2		C2C 402						C2C 40F
offering costs	-		-	27,025		3		626,402		-		-		626,405
Vesting of restricted stock	-		-	1,428		-		-		-		-		200
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	-		-	-		-		-		20		(180.617)		(180,617)
		\$		170.041	ф	- 10	ф.	1 401 050	\$	-	ф.		d.	
Balance as of March 31, 2021	-	\$	-	178,941	\$	18	\$	1,491,958	Э	56	\$	(610,049)	\$	881,983
Vesting of restricted stock	-		-	1,423		-		-		-		-		-
Exercise of stock options	-		-	212		-		333		-		-		333
Stock-based compensation expense	-		-	-		-		4,941		-		-		4,941
Unrealized loss on marketable										(40)				(40)
securities, net	-		-	-		-		-		(43)		40.000		(43)
Net income		_			_			-	_		_	18,683	_	18,683
Balance as of June 30, 2021	-	\$	-	180,576	\$	18	\$	1,497,232	\$	13	\$	(591,366)	\$	905,897
Vesting of restricted stock	-		-	1,628		-		-		-		-		-
Exercise of stock options	-		-	704		-		1,596		-		-		1,596
Stock-based compensation expense	-		-	-		-		5,950		-		-		5,950
Unrealized loss on marketable														
securities, net	-		-	-		-		-		(95)		-		(95)
Net loss	-		-			-		-		-		(83,263)		(83,263)
Balance as of September 30, 2021	-	\$		182,908	\$	18	\$	1,504,778	\$	(82)	\$	(674,629)	\$	830,085

	Convertible Preferred Stock		Commo	Common Stock			Additional Paid-In	Accumulated Other Comprehensive		Accumulated		Total Stockholders		
	Shares		Amount	Shares		mount	-	Capital	Income (Loss)		,	Deficit	310	Deficit
Balance as of December 31, 2019	106,890	\$	417,359	10,003	\$	1	\$		\$	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)
Issuance of Series B convertible preferred												, , ,		,
stock, net of issuance costs of \$33	27,223		435,538	-		-		-		-		-		-
Issuance of common stock in connection with														
license agreement	-		-	63		-		388		-		-		388
Vesting of restricted stock	-		-	1,382		-		-		-		-		-
Exercise of stock options	-		-	24		-		35		-		-		35
Stock-based compensation expense	-		-	-		-		1,116		-		-		1,116
Unrealized gain on marketable														
securities, net	-		-	-		-		-		7		-		7
Net loss			-			-		-		-		(87,808)		(87,808)
Balance as of June 30, 2020	134,113	\$	852,897	12,901	\$	1	\$	3,854	\$	23	\$	(264,810)	\$	(260,932)
Vesting of restricted stock	-		-	1,343		-		-		-		-		-
Exercise of stock options	-		-	6		-		9		-		-		9
Stock-based compensation expense	-		-	-		-		1,168		-		-		1,168
Unrealized gain on marketable														
securities, net	-		-	-		-		-		32		-		32
Net loss			-	-		-		-		-		(51,452)		(51,452)
Balance as of September 30, 2020	134,113	\$	852,897	14,250	\$	1	\$	5,031	\$	55	\$	(316,262)	\$	(311,175)

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

	Nine Months Ended September 30, 2021 2020							
OPERATING ACTIVITIES:								
Net loss	\$	(245,197)	\$	(172,135)				
Adjustments to reconcile net loss to net cash used in operating activities:								
Depreciation		7,735		4,166				
Stock-based compensation expense		15,049		3,037				
Change in the estimated fair value of contingent consideration		10,080		16,672				
Change in the estimated fair value of success payment liabilities		57,698		40,637				
Non-cash expense for operating lease right-of-use assets		4,597		2,889				
Other non-cash items, net		(2,255)		819				
Changes in operating assets and liabilities:								
Prepaid expenses and other assets		(2,985)		682				
Operating lease right-of-use assets and liabilities		5,028		91				
Accounts payable		1,397		2,414				
Accrued expenses and other liabilities		7,898		305				
Net cash used in operating activities		(140,955)		(100,423)				
INVESTING ACTIVITIES:	· <u> </u>	_		_				
Purchases of marketable securities		(414,437)		(307,398)				
Proceeds from sales and maturities of marketable securities		266,960		56,400				
Purchases of property and equipment		(24,660)		(14,606)				
Net cash used in investing activities	<u></u>	(172,137)		(265,604)				
FINANCING ACTIVITIES:								
Proceeds from initial public offering of common stock, net of offering costs		626,405		-				
Proceeds from issuance of convertible preferred stock, net of issuance costs		-		435,538				
Proceeds from exercise of stock options		2,227		46				
Net cash provided by financing activities		628,632		435,584				
Net increase in cash, cash equivalents, and restricted cash		315,540		69,557				
Cash, cash equivalents, and restricted cash at beginning of period		126,949		81,807				
Cash, cash equivalents, and restricted cash at end of period	\$	442,489	\$	151,364				
SUPPLEMENTAL CASH FLOW DISCLOSURES:		_						
Right-of-use assets obtained in exchange for operating lease liabilities	\$	26,257	\$	23,049				
Cash received from lessor for tenant improvement allowance	\$	5,160	\$	91				
Tenant improvement allowance included in operating lease liabilities	\$	4,438	\$	8,515				
Purchases of property and equipment included in accounts payable and accrued liabilities	\$	3,231	\$	4,238				

## Sana Biotechnology, Inc. Notes to Condensed Consolidated Financial Statements

#### 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, establishing manufacturing capabilities, 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 has 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, building out internal and external manufacturing capabilities, competitors developing new technological innovations, the need to successfully commercialize and gain market acceptance of the Company's products, the need to 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 additional equity or debt financings or other capital obtained in connection with strategic collaborations or 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 September 30, 2021, the Company had cash, cash equivalents, and marketable securities of \$866.1 million, and an accumulated deficit of \$674.6 million, which includes non-cash charges of \$131.8 million and \$80.7 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 the preparation of these condensed consolidated financial statements as of September 30, 2021 and for the three and nine months ended September 30, 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). Certain prior period amounts have been reclassified to conform to current period presentation.

#### 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 and nine months ended September 30, 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 Corp. (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 in-process research and development (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 and nine months ended September 30, 2020.

The Oscine Holdback Amount will be held until December 2021, which is 15 months following the consummation of the acquisition, 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 Biomedicine, Inc. (Cobalt), a privately-held early-stage biotechnology company that was 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 has an obligation to pay contingent consideration (Cobalt Contingent Consideration) of up to an aggregate of \$500.0 million to certain former Cobalt stockholders upon the achievement of certain pre-specified development milestones. Additionally, the Company is obligated to pay a success payment (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, including the Company's IPO and periodically thereafter, the Company's market capitalization equals or exceeds \$8.1 billion, and the Company is advancing a 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 from the date of the Cobalt acquisition, but this period could be shorter upon the occurrence of certain events. As of September 30, 2021, a Cobalt Success Payment had not been triggered.

In addition to an IPO, a valuation measurement date would be triggered upon a change of control of the Company if at least one Company product based on the fusogen technology is the subject of an active research program at the time of such change of control. If there is a change of control and the Company's market capitalization is below \$8.1 billion as of the date of the change of control, 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 various thresholds for the Company's market capitalizations as of the date of a change of control and the resulting potential Cobalt Success Payment and additional potential Cobalt Contingent Consideration:

Sana market capitalization upon a change of control and resulting impact to Cobalt Success Payment and additional potential Cobalt Contingent Consideration	 t Success yment	pote C	Additional ential Cobalt Contingent onsideration
	(in mill	ions)	
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 the condensed consolidated statements of operations in research and development related success payments and contingent consideration. As of September 30, 2021 and December 31, 2020, the estimated fair value of the Cobalt Success Payment liability was \$111.6 million and \$64.7 million, respectively, and was recorded in long-term liabilities in the condensed consolidated balance sheets. In connection with the change in the estimated fair value of the Cobalt Success Payment, the Company recognized expenses of \$21.8 million and \$1.3 million for the three months ended September 30, 2021 and 2020, respectively, and expenses of \$46.9 million and \$35.2 million for the nine months ended September 30, 2021 and 2020, respectively.

As of September 30, 2021, the estimated fair value of the Cobalt Contingent Consideration was \$132.0 million, of which \$43.5 million was recorded in short-term liabilities and \$88.5 million was recorded in long-term liabilities in the condensed consolidated balance sheet. As of December 31, 2020, the estimated fair value of the Cobalt Contingent Consideration was \$121.9 million and was recorded in long-term liabilities in the condensed consolidated balance sheet. In connection with the change in the estimated fair value of the Cobalt Contingent Consideration, we recognized a gain of \$8.5 million and an expense of \$2.3 million for the three months ended September 30, 2021 and 2020, respectively, and expenses of \$10.1 million and \$16.7 million for the nine months ended September 30, 2021 and 2020, respectively.

#### 4. Intangible asset and goodwill

As of September 30, 2021, the Company had an intangible asset of \$59.2 million, which consists of 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 September 30, 2021, there was no amortization of the intangible asset. As of September 30, 2021, the Company had goodwill of \$140.6 million, which 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 success payments to Harvard up to an aggregate of \$175.0 million, payable in cash, based on increases in the fair value of the Company's 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 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, the date of the consummation of a merger, an asset sale, or 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 Harvard 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 the fair value of the Company's common stock. 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 would be 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 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

The Harvard Success Payment liabilities are carried at fair value, with changes in fair value recognized on the condensed consolidated statements of operations in research and development related success payments and contingent consideration. As of September 30, 2021 and December 31, 2020, the estimated fair value of the Harvard Success Payment liability was \$22.6 million and \$11.8 million, respectively. As of September 30, 2021 and December 31, 2020, \$5.0 million and \$0, respectively, were recorded in short-term liabilities, and \$17.6 million and \$11.8 million, respectively, were recorded in long-term liabilities in the condensed consolidated balance sheet. For the three months ended September 30, 2021 and 2020, the Company recognized expenses of \$3.4 million and \$0.8 million, respectively, in connection with the change in the estimated fair value of the Harvard Success Payment liability. For the nine months ended September 30, 2021 and 2020, the Company recognized expenses of \$10.8 million and \$5.5 million, respectively, 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 September 30, 2021 and December 31, 2020, the Company maintained standby letters of credit of \$8.8 million and \$2.1 million, respectively, which are collateralized with a bank account at a financial institution in accordance with the applicable 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:

		September 30, 2021										
	Valuation Hierarchy	A	amortized Cost		Gross Inrealized Holding Gains	]	Gross nrealized Holding Losses	I	Estimated Fair Value			
Financial assets:					(in thou	isands)						
Cash equivalents:												
Money market funds	Level 1	\$	379,336	\$	-	\$	-	\$	379,336			
Corporate debt securities	Level 2		121		-		-		121			
Total cash equivalents			379,457	-	-		-		379,457			
Short-term marketable securities:												
U.S. government and agency securities	Level 2		76,538		18		-		76,556			
Corporate debt securities	Level 2		93,504		4		(23)		93,485			
Total short-term marketable securities			170,042		22		(23)		170,041			
Long-term marketable securities:												
U.S. government and agency securities	Level 2		226,861		24		(81)		226,804			
Corporate debt securities	Level 2		35,621		-		(24)		35,597			
Total long-term marketable securities			262,482		24		(105)		262,401			
Total financial assets		\$	811,981	\$	46	\$	(128)	\$	811,899			
Financial liabilities:												
Short-term financial liabilities:												
Contingent consideration	Level 3	\$	43,459	\$	-	\$	-	\$	43,459			
Success payment liabilities	Level 3		5,000		-		-		5,000			
Total short-term financial liabilities			48,459		-		-		48,459			
Long-term financial liabilities:												
Contingent consideration	Level 3		88,522		-		-		88,522			
Success payment liabilities	Level 3		129,192		-		-		129,192			
Total long-term financial liabilities			217,714		-		-		217,714			
Total financial liabilities		\$	266,173	\$	_	\$	_	\$	266,173			

		December 31, 2020									
	Valuation Hierarchy	Ame	ortized Cost	1	Gross Unrealized Holding Gains	Un H I	Gross realized olding Losses	]	Estimated Fair Value		
Financial assets:					(in thou	isanas)					
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 nine months ended September 30, 2021. As such, an allowance for credit losses has not been recognized. As of September 30, 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 September 30, 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 September 30, 2021, the balance in accumulated other comprehensive income (loss) included the net unrealized gains (losses) 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 and nine months ended September 30, 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 - expense (gain)		11,393		91,757		23,900	
Balance as of March 31, 2021		133,294		156,451		35,700	
Changes in fair value - expense (gain)		7,163		(66,632)		(16,556)	
Balance as of June 30, 2021		140,457		89,819		19,144	
Changes in fair value - expense (gain)		(8,476)		21,790		3,439	
Balance as of September 30, 2021	\$	131,981	\$	111,609	\$	22,583	

#### **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:

	Septemb	er 30, 2021	Decembe	r 31, 2020
Unobservable Input	Range	Range Weighted-Average		Weighted-Average
Discount rates	10.8% - 11.6%	11.1%	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:

	Septem	ber 30, 2021	Decembe	er 31, 2020
Unobservable Input	Cobalt	Harvard	Cobalt	Harvard
Expected stock price volatility	70%	70%	70%	70%
Expected term (years)	17.4	9.5	18.1	10.2

#### 8. Property and equipment, net

Property and equipment, net consists of the following:

	September	r 30, 2021	Decemb	er 31, 2020
Laboratory equipment	\$	41,585	\$	26,958
Leasehold improvements		26,109		15,598
Construction in progress		10,293		11,180
Computer equipment, software, and other		930		776
Total property and equipment, at cost		78,917		54,512
Less: Accumulated depreciation		(15,472)		(7,737)
Property and equipment, net	\$	63,445	\$	46,775

Depreciation expense was \$2.8 million and \$1.6 million for the three months ended September 30, 2021 and 2020, respectively, and \$7.7 million and \$4.2 million for the nine months ended September 30, 2021 and 2020, respectively.

#### 9. Accrued liabilities

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

	Septe	ember 30, 2021	Decei	mber 31, 2020
		(in tho	usands)	
Accrued compensation:				
Accrued bonuses	\$	9,670	\$	11,582
Accrued payroll		5,543		1,660
Accrued paid time off		4,981		2,441
Other accrued compensation		24		337
Total accrued compensation	\$	20,218	\$	16,020
Accrued expenses and other current liabilities:				
Accrued research and development	\$	4,358	\$	1,197
Accrued property and equipment		3,178		2,892
Accrued professional fees		2,209		1,717
Other accrued current liabilities		3,139		3,660
Total accrued expenses and other current liabilities	\$	12,884	\$	9,466

#### 10. Commitments and contingencies

#### Lease commitments

The Company's lease portfolio is primarily comprised of operating leases for office, laboratory, non-good manufacturing practices (GMP) pilot plant manufacturing, and industrial space located in Seattle, WA, Cambridge, MA, South San Francisco, CA and Fremont, CA. Operating leases have contractual periods expiring between April 2024 and November 2031. 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 each 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 for these leases. The industrial space located in Fremont, CA will be used for the construction of a GMP manufacturing facility. The lease agreement initial term is ten years and includes the option to extend for up to two additional five-year terms. The Company anticipates that it will exercise both options to extend. Certain leases provide the Company with the right to make tenant improvements, including the addition of laboratory space or build-out of manufacturing capabilities, 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 September 2021	April 2024 to April 2030
Fremont, CA	163,193	July 2021	November 2031

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:

	T	Three Months Ended September 30,				Nine Months Ended September 30,				
	20	21		2020		2021		2020		
				(in thou	ısands)					
Operating lease cost	\$	4,303	\$	2,750	\$	11,368	\$	7,870		
Short-term lease cost		-		474		512		1,418		
Variable lease cost		1,286		837		4,015		2,306		
Total lease cost	\$	5,589	\$	4,061	\$	15,895	\$	11,594		

As of September 30, 2021, the weighted-average remaining lease term was 7.9 years and the weighted-average incremental borrowing rate was 9.55%.

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 September 30, 2021 (in thousands):

2021 (remaining 3 months)	\$	2,867
2022		17,511
2023		17,677
2024		17,036
2025		17,151
2026 and thereafter		98,614
Total undiscounted lease payments	_	170,856
Less: imputed interest		(67,513)
Less: tenant improvement allowances		(4,438)
Present value of operating lease liabilities	\$	98,905

#### 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 September 30, 2021.

#### 12. Stockholders' equity

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 September 30, 2021, there were 182.9 million shares of the Company's common stock outstanding, excluding 5.8 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 Incentive 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. The 2018 Plan terminated as of the adoption of the 2021 Incentive Award Plan.

#### Stock-based compensation expense

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

	Thi	Three Months Ended September 30,				Nine Months Ended September 30,			
		2021		2020	2021			2020	
				(in thou	ısands)				
Research and development	\$	4,072	\$	980	\$	9,888	\$	2,555	
General and administrative		1,878		186		5,161		482	
Total stock-based compensation expense	\$	5,950	\$	1,166	\$	15,049	\$	3,037	

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 September 30, 2021 are as follows:

	Stock Options	RSAs		RSUs
Unrecognized stock-based compensation expense (in thousands)	\$ 79,637	\$	2,166	\$ 887
Weighted-average period costs expected to be recognized (years)	2.8		1.1	1.5

#### 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	3,398		23.26		
Exercised	(1,121)		1.99		
Forfeited/Cancelled	(671)		5.05		
Outstanding as of September 30, 2021	17,283	\$	8.34	8.9	\$ 244,590
Exercisable as of September 30, 2021	2,874	\$	2.05	8.2	\$ 58,832

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:

	Nine Months Ended	September 30,
Assumptions	2021	2020
Risk free interest rate	0.46% - 1.15%	0.36% - 1.51%
Expected volatility	70%	70%
Expected term (years)	5.50 - 6.40	6.25 - 6.75
Expected dividend	0%	0%

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

	1	·					
		2021	202	20			
Weighted average grant date fair value per share for options granted	\$	14.64	\$	0.54			
Aggregate intrinsic value of stock options exercised (in thousands)	\$	22,187	\$	205			
19							

#### Restricted stock awards

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

	RSAs (in thousands)	Gra	ghted-Average ant Date Fair ue per Share
Unvested shares as of December 31, 2020	10,079	\$	0.33
Vested	(4,273)		0.25
Forfeited	(15)		0.73
Unvested shares as of September 30, 2021	5,791	\$	0.39

The fair value of vested RSAs for the three months ended September 30, 2021 and 2020 was \$0.4 million and \$0.2 million, respectively, and \$1.1 million and \$0.6 million for the nine months ended September 30, 2021 and 2020, respectively. As of December 31, 2020, there were 0.3 million RSUs unvested. During the nine months ended September 30, 2021 there were 0.1 million granted, 0.2 million vested. As of September 30, 2021, there are 0.2 million RSUs unvested.

#### 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 summarizes the calculation of basic and diluted net loss per share of common stock:

		Three Months End	led Sej	otember 30,		Nine Months Ende	ember 30,					
		2021		2020		2021		2020				
	(in thousands, except per share amounts)											
Net loss	\$	(83,263)	\$	(51,452)	\$	(245,197)	\$	(172,135)				
Weighted-average number of common shares - basic and diluted		181,827		13,680		160,515		12,249				
Net loss per common share - basic and diluted	\$	(0.46)	\$	(3.76)	\$	(1.53)	\$	(14.05)				

The following securities were excluded from the computation of net loss per diluted share of common stock for periods presented as their effect would have been anti-dilutive:

	Nine Months Ende	d September 30,					
	2021	2020					
	(in thousands)						
Convertible preferred stock	-	134,113					
Options issued and outstanding	17,284	9,677					
Unvested restricted common stock	5,791	11,952					
Unvested RSUs	150	326					
Total	23,225	156,068					

#### 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.

#### 17. Subsequent events

In October 2021, the Company entered into an Option and License Agreement with Beam Therapeutics Inc. (Beam), pursuant to which Beam granted to the Company a non-exclusive license to use Beam's proprietary CRISPR Cas12b nuclease editing technology to research, develop and commercialize engineered cell therapy products that (i) are directed to certain antigen targets, with respect to the Company's allogeneic T cell programs, or (ii) comprise certain human cell types, with respect to the Company's stem cell-derived programs. Pursuant to the agreement, the Company made an upfront payment of \$50.0 million to Beam. Additionally, the Company will be obligated to pay to Beam up to \$65.0 million for each licensed product in specified developmental and commercial milestone payments and royalties on licensed products. A member of the Company's board of directors is a beneficial owner of greater than 10% of the outstanding shares of Beam and is affiliated with a member of the board of directors of Beam.

#### 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:

PLATFORM	TECHNOLOGY	PROGRAMS		POTENTIAL	POTENTIAL IND SUBMISSION	PRE-	PH	IASE		
PLATFORM	TECHNOLOGY	(CELL TYPES)	AREA	CANDIDATE	INDICATIONS	SORIVISSION	CLINICAL	1	2	3
				SG295 (CD8/CD19)	NHL/ALL/CLL	As early as 2022				
		T cells	Oncology	SG239 (CD8/BCMA)	Multiple myeloma	As early as 2024				
		SG242 (CD4/CD19)	NHL/ALL/CLL	As early as 2023						
In vivo cell engineering	Fusogen			SG221 (CD4/BCMA)	Multiple myeloma	As early as 2024				
		Hepatocytes	Liver-related genetic disorders	SG328	Ornithine transcarbamylase deficiency	As early as 2023				
		Hematopoietic	Hemoglobinopathies	SC410	Sickle cell disease	As early as 2023				
		stem cells	Tiemoglobinopatries	00410	Beta-thalassemia	As early as 2023				
	Hypoimmune	mmune T cells	Oncology	SC291 (CD19)	NHL/ALL/CLL	As early as 2022				
	donor-derived	i cells		SC255 (BCMA)	Multiple myeloma	As early as 2023				
	Hypoimmune stem cell-derived	Beta cells	Diabetes	SC451	Type 1 diabetes	As early as 2023				
Ex vivo cell engineering					Huntington's disease	As early as 2023				
	Stem cell-derived (to migrate to	Glial progenitor cells	Central nervous system (CNS)	SC379	Pelizaeus-Merzbacher disease	As early as 2023				
	hypoimmune)				Secondary progressive multiple sclerosis	As early as 2023				
		Cardiomyocytes	Cardiovascular	SC187	Heart failure	As early as 2023				

We continue to make scientific progress on developing our cell engineering platforms and advancing our product candidates through preclinical development and towards potential IND submissions. Given the depth and breadth of our portfolio, we expect to assess and prioritize our programs on an ongoing basis based on various factors, including internal and external opportunities and constraints, which may result in our decision to advance certain programs ahead or instead of others. As certain of our product candidates advance towards potential IND submissions, we are conducting GLP toxicity studies and establishing necessary scale-up for our manufacturing processes.

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, hypoimmune technology licensed from the President and Fellows of Harvard College (Harvard) and The Regents of the University of California, and genome editing technology licensed from Beam Therapeutics Inc. (Beam), amongst others. For details regarding these acquisitions and license and collaboration agreements, see Note 3, Acquisitions and Note 5, License and collaboration agreements, 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. For details regarding our option and license agreement with Beam, see Note 17, Subsequent events, to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report.

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, establishing manufacturing capabilities, 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 for the nine months ended September 30, 2021 and 2020 were \$245.2 million and \$172.1 million, respectively. As of September 30, 2021, we had an accumulated deficit of \$674.6 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, as of September 30, 2021, the accumulated deficit of \$674.6 million includes non-cash charges of \$131.8 million and \$80.7 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 September 30, 2021, we had cash, cash equivalents, and marketable securities of \$866.1 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 approximately 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 facility; 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; 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, including establishing an internal manufacturing facility.

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 that are 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 pandemic and its impact on our ability to build out and operationalize our manufacturing facility, clinical trial enrollment, trial sites, contract research organizations (CROs), contract manufacturing organizations, suppliers of key materials and supplies, including raw materials, consumables, and other equipment necessary to manufacture our product candidates, 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 17, Subsequent events, to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report, Note 5, License and collaboration agreements, to our consolidated financial statements included in our 2020 Form 10-K, and 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 have an obligation to pay contingent consideration (Cobalt Contingent Consideration) of up to an aggregate of \$500.0 million to certain former Cobalt stockholders upon our achievement of certain pre-specified development milestones (Cobalt Contingent Consideration), and a success payment (Cobalt Success Payment) of up to \$500.0 million payable in cash or stock, at our discretion. The Cobalt Success Payment is payable, if at pre-determined valuation measurement dates, including our IPO and periodically thereafter, our market capitalization equals or exceeds \$8.1 billion, and we are advancing 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). As of September 30, 2021, a Cobalt Success Payment had not been triggered. In addition to our IPO, a valuation measurement date would be triggered upon a change of control if at least one of our programs based on the fusogen technology is the subject of an active research program at the time of such change of control. If there is a change of control and our market capitalization is below \$8.1 billion as of the date of the change of control, 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 September 30, 2021 and December 31, 2020, the estimated fair value of the Cobalt Success Payment liability was \$111.6 million and \$64.7 million, respectively, and was recorded in long-term liabilities in the condensed consolidated balance sheets. In connection with the change in the estimated fair value of the Cobalt Success Payment, we recognized expenses of \$21.8 million and \$1.3 million for the three months ended September 30, 2021 and 2020, respectively, and expenses of \$46.9 million and \$35.2 million for the nine months ended September 30, 2021 and 2020, respectively.

As of September 30, 2021, the estimated fair value of the Cobalt Contingent Consideration was \$132.0 million, of which \$43.5 million was recorded in short-term liabilities and \$88.5 million was recorded in long-term liabilities in the condensed consolidated balance sheet. As of December 31, 2020, the estimated fair value of the Cobalt Contingent Consideration of \$121.9 million was recorded in long-term liabilities in the condensed consolidated balance sheet. In connection with the change in the estimated fair value of the Cobalt Contingent Consideration, we recognized a gain of \$8.5 million and expense of \$2.3 million for the three months ended September 30, 2021 and 2020, respectively, and expenses of \$10.1 million and \$16.7 million for the nine months ended September 30, 2021 and 2020, 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" and "—Critical accounting policies and significant judgments and estimates—Contingent consideration" in our 2020 Form 10-K for more information on the accounting treatment of the Cobalt Success Payment and Cobalt Contingent Consideration.

#### 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 September 30, 2021 and December 31, 2020, the estimated fair value of the Harvard Success Payment liability was \$22.6 million and \$11.8 million, respectively. As of September 30, 2021 and December 31, 2020, \$5.0 million and \$0, respectively, were recorded in short-term liabilities, and \$17.6 million and \$11.8 million, respectively, were recorded in long-term liabilities in the condensed consolidated balance sheet. In connection with the change in the estimated fair value of the Harvard Success Payment

liability, we recognized expenses of \$3.4 million and \$0.8 million for the three months ended September 30, 2021 and 2020, respectively, and expenses of \$10.8 million and \$5.5 million for the nine months ended September 30, 2021 and 2020, 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 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. The timing and amount of costs to acquire and license technologies in the future cannot be estimated with reliability and may 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. 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, establishing internal and external manufacturing capabilities, 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.

Research and development related success payments and contingent consideration

Research and development related success payments and contingent consideration include the change in the estimated fair value of our Cobalt and Harvard Success Payment liabilities and Cobalt Contingent Consideration. Research and development expense (gain) 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 calculations.

#### 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, 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 continuing to incur 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 and nine months ended September 30, 2021 and 2020

The following table summarizes our results of operations for the periods presented (in thousands):

	Three Mon Septem									
	2021		2020		Change	2021		2020		Change
Operating expenses:										
Research and development	\$ 53,245	\$	40,056	\$	13,189	\$	140,121	\$	96,453	\$ 43,668
Research and development related success payments and contingent										
consideration	16,753		4,489		12,264		67,778		57,309	10,469
General and administrative	13,433		7,099		6,334		37,731		19,063	18,668
Total operating expenses	83,431		51,644		31,787		245,630		172,825	72,805
Loss from operations	 (83,431)		(51,644)		(31,787)		(245,630)		(172,825)	(72,805)
Interest income, net	158		148		10		409		622	(213)
Other income, net	10		44		(34)		24		68	(44)
Net loss	\$ (83,263)	\$	(51,452)	\$	(31,811)	\$	(245,197)	\$	(172,135)	\$ (73,062)

#### Research and development expenses

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

	Three Months Ended September 30,						
		2021	2020			Change	
	(in thousands)						
Personnel	\$	20,477	\$	12,054	\$	8,423	
Research and laboratory		17,938		10,632		7,306	
Facility and other allocated costs		13,694		8,019		5,675	
Acquisition and licensing of technology		213		8,956		(8,743)	
Other		923		395		528	
Total research and development expense	\$	53,245	\$	40,056	\$	13,189	

Research and development expense was \$53.2 million and \$40.0 million for the three months ended September 30, 2021 and 2020, respectively. The increase of \$13.2 million was primarily due to:

- increased personnel-related expenses of \$8.4 million, including non-cash stock-based compensation of \$3.1 million, which was primarily attributable to an increase in headcount to expand our research and development capabilities;
- an increase of \$7.3 million in research and laboratory costs, including laboratory supplies, preclinical studies, third-party manufacturing costs, and other external research expenses; and
- · an increase of \$5.2 million of facility and allocated costs, including rent, depreciation, and allocated overhead costs.

The increases were offset by a decrease in upfront license fees of \$8.7 million, primarily due to the upfront expense of \$8.5 million recorded in the three months ended September 30, 2020 related to the acquisition of Oscine Corp.

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

	Nine Months Ended September 30,							
		2021		2020		Change		
	(in thousands)							
Personnel	\$	55,230	\$	33,288	\$	21,942		
Research and laboratory		46,036		28,453		17,583		
Facility and other allocated costs		34,800		21,519		13,281		
Acquisition and licensing of technology		1,845		11,352		(9,507)		
Other		2,210		1,841		369		
Total research and development expense	\$	140,121	\$	96,453	\$	43,668		

Research and development expense was \$140.1 million and \$96.4 million for the nine months ended September 30, 2021 and 2020, respectively. The increase of \$43.7 million was primarily due to:

- increased personnel-related expenses of \$21.9 million, including non-cash stock-based compensation of \$7.3 million, which was primarily
  attributable to an increase in headcount to expand our research and development capabilities;
- an increase of \$17.6 million in research and laboratory costs, including preclinical studies, laboratory supplies, third-party manufacturing costs, and other external research expenses; and
- · an increase of \$12.4 million of facility and allocated costs, including rent, depreciation, and allocated overhead costs.

The increases were offset by a decrease in upfront license fees of \$9.5 million, primarily due to the upfront expense of \$8.5 million recorded in the nine months ended September 30, 2020 related to the acquisition of Oscine Corp.

Research and development related success payments and contingent consideration

The following table summarizes the expenses (gains) associated with research and development related success payments and contingent consideration for the periods presented:

	Th	ree Months End						
		2021		2020		Change		
	(in thousands)							
Success payments	\$	25,229	\$	2,156	\$	23,073		
Contingent consideration		(8,476)		2,333		(10,809)		
Total research and development related success payments and contingent consideration	\$	16,753	\$	4,489	\$	12,264		

For the three months ended September 30, 2021 and 2020, we recognized net non-cash expenses of \$16.8 million and \$4.5 million, respectively, for the changes in the estimated fair value of research and development related success payments and contingent consideration. The expense related to the change in the estimated fair value of our Cobalt Success Payment and Harvard Success Payment liabilities in aggregate was \$25.2 million for the three months ended September 30, 2021 compared to \$2.2 million for the same period in 2020. The change in the estimated fair value of the success payment liabilities was due to increases in our market capitalization and common stock price during the relative periods. We recorded a gain in the three months ended September 30, 2021 of \$8.5 million for the change in the estimated fair value of our Cobalt Contingent Consideration and an expense of \$2.3 million for the same period in 2020. The change in the estimated fair value of the Cobalt Contingent Consideration was primarily due to an increase in the discount rate used in the calculation and scientific progress toward the achievement of milestones during the relative periods.

The following table summarizes the expenses associated with research and development related success payments and contingent consideration for the for the periods presented:

	Nine Months Ended September 30,							
		2021		2020	(	Change		
Success payments	\$	57,698	\$	40,637	\$	17,061		
Contingent consideration		10,080		16,672		(6,592)		
Total research and development related success payments and contingent consideration	\$	67,778	\$	57,309	\$	10,469		

For the nine months ended September 30, 2021 and 2020, we recognized non-cash expenses of \$67.8 million and \$57.3 million, respectively, for the changes in the estimated fair value of research and development related success payments and contingent consideration. The expense related to the change in the estimated fair value of our Cobalt Success Payment and Harvard Success Payment liabilities in aggregate was \$57.7 million for the nine months ended September 30, 2021 compared to \$40.6 million for the same period in 2020. The change in the estimated fair value of the success payment liabilities was due to increases in our market capitalization and common stock price during the relative periods. The expense related to the change in the estimated fair value of our Cobalt Contingent Consideration was \$10.1 million for the nine months ended September 30, 2021 compared to \$16.7 million for the same period in 2020. The change in the estimated fair value of the Cobalt Contingent Consideration was primarily due to scientific progress toward the achievement of milestones during the relative periods.

#### General and administrative Expenses

General and administrative expenses were \$13.4 million and \$37.7 million for the three and nine months ended September 30, 2021, respectively, compared to \$7.1 million and \$19.1 million for the three and nine months ended September 30, 2020, respectively.

The increase of \$6.3 million for the three months ended September 30, 2021 was primarily due to increased personnel-related expenses of \$3.5 million, including non-cash stock-based compensation of \$1.7 million, primarily attributable to an increase in headcount to build our infrastructure, increased legal fees to support our patent portfolio and licensing arrangements of \$1.3 million, and increased insurance of \$1.0 million associated with being a public company.

The increase of \$18.6 million for the nine months ended September 30, 2021 was primarily due to increased personnel-related expenses of \$8.7 million, including non-cash stock-based compensation of \$4.7 million, primarily attributable to an increase in headcount to build our infrastructure, increased legal fees to support our patent portfolio and licensing arrangements of \$3.7 million, increased insurance of \$3.0 million associated with being a public company, increased consulting fees of \$1.0 million, and facility costs, including rent, of \$0.9 million.

#### Interest income, net

Interest income, net was \$0.2 million and \$0.4 million for the three and nine months ended September 30, 2021, respectively, compared to \$0.2 million and \$0.6 million for the three and nine months ended September 30, 2020, respectively.

#### Liquidity, capital resources, and capital requirements

#### Sources of liquidity

As of September 30, 2021, we had \$866.1 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 approximately 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 associated with building our manufacturing capabilities, as well as costs associated with the manufacturing of 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;
- our ability to address 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 obtained in connection with strategic collaborations or licensing or other arrangements. In the event that additional financing is required, we may not be able to raise it on terms that are 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 or 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:

	 Nine Months Ended September 30,							
	2021		2020					
	(in thousands)							
Net cash provided by (used in):								
Operating activities	\$ (140,955)	\$	(100,423)					
Investing activities	(172,137)		(265,604)					
Financing activities	 628,632		435,584					
Net increase in cash, cash equivalents, and restricted cash	\$ 315,540	\$	69,557					

#### Operating activities

During the nine months ended September 30, 2021, net cash used in operating activities was \$141.0 million, consisting primarily of our net loss of \$245.2 million, partially offset by the change in our net operating assets and liabilities of \$11.3 million and non-cash charges of \$92.9 million. The non-cash charges of \$92.9 million consisted of \$57.7 million for revaluation of our success payment liabilities, \$10.1 million for revaluation of contingent consideration, non-cash stock-based compensation expense of \$15.0 million, depreciation expense of \$7.7 million, and other non-cash charges of \$2.4 million.

During the nine months ended September 30, 2020, net cash used in operating activities was \$100.4 million, consisting of our net loss of \$172.1 million, partially offset by non-cash charges of \$68.2 million and the change in our net operating assets and liabilities of \$3.5 million. The non-cash charges of \$68.2 million consisted of \$40.6 million for revaluation of success payment liabilities, \$16.7 million for revaluation of contingent consideration, depreciation expense of \$4.2 million, non-cash stock-based compensation expense of \$3.0 million, and other non-cash charges of \$3.7 million.

#### Investing activities

During the nine months ended September 30, 2021, cash used in investing activities was \$172.1 million. This consisted primarily of sales and maturities, less purchases, of marketable securities of \$147.4 million and purchases of property and equipment of \$24.7 million. During the nine months ended September 30, 2020, cash used in investing activities was \$265.6 million, consisting primarily of net purchases, sales, and maturities of marketable securities of \$251.0 million and purchases of property and equipment of \$14.6 million.

#### Financing activities

During the nine months ended September 30, 2021, cash provided by financing activities was \$628.6 million, consisting primarily of net proceeds from our IPO of \$626.4 million. During the nine months ended September 30, 2020, cash provided by financing activities was \$435.6 million, consisting primarily of proceeds from the sale of our convertible preferred stock.

#### **Contractual obligations and commitments**

The following table summarizes our significant contractual obligations and commitments as of September 30, 2021:

		Payments Due by Period										
	Le	Less than 1 Year 1 to 3 Years				3 to 5 Years	N	Iore than 5 Years		Total		
						(in thousands)						
Operating lease obligations	\$	16,033	\$	34,850	\$	34,568	\$	85,405	\$	170,856		

Other than as disclosed in the table above, the payment obligations under our license, collaboration, and acquisition agreements as of September 30, 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 September 30, 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 September 30, 2021 and for the three and nine months ended September 30, 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 common stock price.

#### Interest Rate Risk

As of September 30, 2021, we had cash, cash equivalents, and restricted cash of \$442.5 million, which consisted of bank deposits and money market funds. We also had marketable securities of \$432.4 million as of September 30, 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 September 30, 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 September 30, 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 September 30, 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 September 30, 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 or 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. Moreover, we may have already experienced the circumstances described in one or more of the risk factors described below. Many of the following risks and uncertainties are, and will continue to 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 risks and uncertainties described in this "Risk factors" section. This summary does not address every aspect of our risk 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 none have 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 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 ongoing COVID-19 pandemic could materially and adversely affect our preclinical studies and development, our manufacturing capabilities, including with respect to our ability to build out and operationalize our manufacturing

facility and our ability to obtain key materials, consumables and equipment necessary to manufacture our product candidates, any clinical trials we subsequently commence, and our business, financial condition, and results of operations.

- We will require additional funding in order to finance our 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 historically through private placements of our convertible preferred stock and, more recently, through our IPO. We expect that it will be several years, if ever, before we have a commercialized product and generate revenue from product sales. We had net losses of \$245.2 million and \$172.1 million for the nine months ended September 30, 2021 and 2020, respectively. As of September 30, 2021, we had an accumulated deficit of \$674.6 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 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, establish internal and external manufacturing capabilities, continue preclinical studies and commence and advance through 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 and advance through 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, establishing manufacturing capabilities, 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 or 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, and 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 increases in the amount of expenses we will incur 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 our ability to obtain commercial revenue could be further delayed and become more uncertain, which will have a material adverse impact on our business.

We will require additional funding in order to finance our 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 from private placements of our convertible preferred stock and, more recently, our IPO. 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, advance our product candidates into and through 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 September 30, 2021, we had \$866.1 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 as of September 30, 2021, will be sufficient to fund our operating expenses and capital expenditure requirements for approximately 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 associated with building our manufacturing capabilities, as well as costs associated with the manufacturing of 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; or
- 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, payable 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 will not exceed an aggregate of \$175.0 million, which would only occur upon a 40x increase in the fair value of our common stock. 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 our IPO, and periodically thereafter, the date of the consummation of a merger, an asset sale, or 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.

In connection with the Cobalt acquisition, we have an obligation to pay contingent consideration (Cobalt Contingent Consideration) of up to an aggregate of \$500.0 million to certain former Cobalt stockholders upon our achievement of certain pre-defined development milestones. Additionally, we are obligated to pay a success payment to certain Cobalt shareholders (Cobalt Success Payment) of \$500.0 million if, at pre-determined valuation measurement dates, including our IPO and periodically thereafter, our market capitalization equals or exceeds \$8.1 billion, and we are advancing 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 our IPO, a valuation measurement date would be triggered upon a change of control if at least one of our programs based on the fusogen technology is the subject of an active research program at the time of such change of control. If there is a change of control and our market capitalization is below \$8.1 billion as of the date of the change of control, 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 the Cobalt acquisition. See Note 3, Acquisitions, to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report for details on the different company valuation thresholds and the impact on the value of the potential Cobalt Success Payment and potential Cobalt Contingent Consideration following 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 obligations 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 our IPO. See Note 5, License and collaboration agreements, to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report for the per share common stock prices that trigger a Harvard Success Payment and the corresponding payment amount. The first valuation measurement date for the Cobalt Success Payment was our IPO, but our IPO did not trigger such a payment. However, the triggering of 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 our operating results, net losses, and financial condition as reported by U.S. generally accepted accounting principles (GAAP) 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 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 related success payments and contingent consideration. 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 our contingent consideration obligations include, among others, the estimated likelihood and timing within which milestones may be achieved and the estimated discount rates. A small change in the inputs and related assumptions with respect to our success payment and contingent consideration liabilities may result in a relatively large change in the estimated valuation and associated liabilities and resulting expense or gain. As a result, our operating results, net losses, and financial condition as reported by GAAP may fluctuate significantly from quarter to quarter and year to year for reasons unrelated to our operations, which may reduce the usefulness of our GAAP financial statements. For example, as of September 30, 2021, June 30, 2021, March 31, 2021, and December 31, 2020, the estimated aggregate fair value of the Cobalt Success Payment and Harvard Success Payments liabilities was \$134.2 million, \$109.0 million, \$133.3 million, and \$76.5 million, respectively, and the estimated fair value of the Cobalt Contingent Consideration was \$132.0 million, \$140.5 million, \$133.3 million, and \$121.9 million, respectively.

For the three and nine months ended September 30, 2021, we recorded a gain of \$8.5 million and expense of \$10.1 million, respectively, related to the change in the estimated fair value of the Cobalt Contingent Consideration. For the three and nine months ended September 30, 2021, we recorded expenses of \$25.2 million and \$57.7 million, respectively, related to the aggregate change in the estimated fair value of these success payment liabilities. Moreover, for the Harvard Success Payments, keeping all other variables constant, a hypothetical 20% increase in our common stock price at September 30, 2021 from \$22.52 per share to \$27.02 per share would have increased the expense recorded in the three months ended September 30, 2021 associated with the success payment liability by \$5.6 million to \$9.0 million. A hypothetical 20% decrease in the common stock price from \$22.52 per share to \$18.02 per share would have decreased the expense recorded in three months ended September 30, 2021 of \$3.4 million to zero and resulted in a gain of \$2.2 million. For the Cobalt Success Payment, keeping all other variables constant, a hypothetical 20% increase in our market capitalization at September 30, 2021 from \$4.2 billion to \$5.1 billion would have increased the expense recorded in the three months ended September 30, 2021 associated with the success payment liability by \$22.7 million to \$44.5 million. A hypothetical 20% decrease in our market capitalization from \$4.2 billion to \$3.4 billion would have decreased the expense recorded in the three months ended September 30, 2021 of \$21.8 million associated with the success payment liability to zero and resulted in a gain of \$2.4 million.

Although we have incurred net losses in each period since our inception and expect to continue to incur net losses for the foreseeable future, we recorded net income for the three months ended June 30, 2021 due solely to the decrease in the estimated fair value of our success payment liabilities. It is possible that future fluctuations in the price of our common stock and market capitalization and the resulting change in the estimated fair value of our success payment liabilities could again lead us to record net

income in a future period despite us incurring operating losses and negative cash flows during such period. Alternatively, significant stock appreciation during a future period could lead to a significant increase in our recorded GAAP net loss.

### 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, establishing manufacturing capability, 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. Since all of our product candidates are still in preclinical 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 iPSCderived 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 our cell engineering platforms on all pluripotent and differentiated cell types or in all microenvironments, so results from one cell type or microenvironment may not translate into other cells types or microenvironments. Also, we have not tested any of the product candidates that we are developing 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, gene-editing approaches may edit the genome at sites other than the intended DNA target 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 in future clinical trials of our product candidates 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 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 that we develop 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 or

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 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, and any comparable foreign regulatory authority, agree with the design, endpoints, and implementation;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- receipt of 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;
- ability to address 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
- ability to establish, scale up and scale 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 allogeneic 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 September 30, 2021, we had 354 full-time employees. We expect continued growth in the number of our employees and the scope of our operations, particularly as we advance our IND-enabling studies, establish regulatory, quality, and clinical operations, and continue to establish supply chain logistics and manufacturing.

To manage our anticipated future growth, we plan to 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 third parties; and improving our operational, financial and management controls, reporting systems, and procedures.

We currently rely on third-party service providers, 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 such third-party service providers, 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 such third-party service providers, advisors or consultants is unsatisfactory or 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 third-party service providers, advisors or consultants or find other competent third-party service providers, advisors or consultants on reasonable terms, or at all.

## The ongoing COVID-19 pandemic 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 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 periodically 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 limited operations in our executive offices, with our administrative employees primarily continuing their work outside of our offices, 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 may 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 trials as a result of COVID-19 or similar pandemics may 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, developing 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 delivery systems with respect to materials and reagents;
- diversion of healthcare resources away from the conduct of our 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; 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 COVID-19 pandemic 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 geographic spread of the disease, the duration of the pandemic, travel restrictions, actions to contain the pandemic or reduce its impact in the United States and other countries, such as required social distancing, quarantines or lock-downs, 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. If our 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.

Further, certain of our key employees, including Drs. Terry Fry, Steve Goldman and Chuck 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 2022 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. Specifically, 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. We face competition for personnel from other companies, universities, public and private research institutions, and other organizations. 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), and genome editing technology licensed from Beam Therapeutics Inc., 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, including 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 transactions;
- 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 acquired businesses into our businesss.

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, or require us to incur debt, contingent liabilities or amortization expenses or write-offs of goodwill, any of which could harm our financial condition.

Though many of our personnel have significant experience with respect to manufacturing biopharmaceutical products, we, as a company, do not have experience in developing or maintaining a manufacturing facility. There can be no assurance that we will be able to maintain a compliant facility and manufacture our product candidates as intended, given the complexity of manufacturing novel therapeutics. If we fail to successfully operate our facility, this 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.

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.

A key to our strategy is operating our own manufacturing facility. Accordingly, in July 2021, we entered into a long-term lease to establish and operate our own current good manufacturing practices (cGMP) manufacturing facility to support our late-stage clinical development and early commercial product candidates across our product portfolio, including with respect to the production of allogeneic T cells, viral vectors, and pluripotent stem cellderived products. We expect that it will take several years before we are able to begin manufacturing our product candidates at this facility, if at all. Designing and building out our manufacturing facility will be time-consuming and will require significant resources, including a reallocation of certain of our resources, including the time and attention of our senior management. In addition, given the volatility in the costs of building materials, building out our manufacturing facility may be more expensive than we expect. We do not have experience as a company in developing a manufacturing facility, and we may experience unexpected costs or delays or be unsuccessful in developing our internal manufacturing capability in time to support registration-enabling clinical trials of our product candidates or at all. In order to build out the facility, we will need to engage third party service providers and obtain equipment and third-party technology necessary to manufacture our product candidates at the facility; however, we may not be able to negotiate agreements with third parties or access necessary technologies on commercially reasonable terms or at all. Moreover, there is no guarantee that the industrial space that we are leasing to develop our manufacturing facility will not change ownership over the term of the lease or be subject to additional zoning or other restrictions, and that, in such an event, we will be able to continue to build or operate our manufacturing facility without further delay or cost. In addition, operating our facility will require us to continue to hire and retain experienced scientific, quality control, quality assurance and manufacturing personnel. As described elsewhere in these Risk Factors, competition for qualified personnel in the biotechnology and pharmaceutical industries is intense, and if we fail to attract qualified personnel or retain and motivate our current personnel, we will not be able to operate our facility, and our business and future growth prospects would be harmed.

Until we are able to begin manufacturing our product candidates at our facility, we will rely on third-party contract manufacturers to manufacture our product candidates for preclinical and clinical testing. Once we have completed the build-out of our manufacturing facility, we will be required to transition manufacturing processes and know-how of our product candidates from our contract manufacturers to our facility. Transferring manufacturing processes and know-how is complex and involves review and incorporation of both documented and undocumented processes that may have evolved over time. In addition, transferring production to our facility may require utilization of new or different processes to meet the requirements of our facility. Additional studies may also need to be conducted to support the transfer of certain manufacturing processes and process improvements. We cannot be certain that all relevant know-how and data has been adequately incorporated into the manufacturing process until the completion of studies and evaluations intended to demonstrate the comparability of material previously produced by our contract manufacturers with that generated by our facility.

Operating our manufacturing facility will require us to comply with complex regulations. Moreover, our manufacturing facility, and any future commercial manufacturing facilities we may build, will require FDA or comparable foreign regulatory authority approval, which we may not obtain in time to support registration-enabling clinical trials for our product candidates, if at all. 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 cGMP, 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 our manufacturing facility, or any future 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. Any failure or delay in the development of our manufacturing capabilities could adversely impact the development of our product candidates.

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 upon 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 of 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 we can conduct using stem cells, our ability to develop our *ex vivo* cell engineering product candidates may be impaired, and this 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, patients in our clinical trials may experience unexpected side effects and we may experience unexpected regulatory delays prior to approval, or after regulatory approval, if an approval were to occur. Furthermore, our ex vivo stem cell-derived and allogeneic T cell 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 such 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

Our product candidates must successfully progress through extensive preclinical studies and clinical trials in order to obtain regulatory approval to market and sell such product candidates. Even if we obtain positive results in preclinical studies of a product candidate, these results 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 conducted 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 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 during the course of 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 subsequent clinical trials on human subjects. Product candidates may fail to show the desired pharmacological properties or safety and efficacy traits in clinical trials despite having progressed through preclinical studies.

If we fail to obtain 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 none have 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, 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 earlier clinical trials. Our future clinical trials 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 (IRB) approval at each site;
- delays in or failure to reach agreement on acceptable terms, or at all, 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 that could cause us or governmental authorities, as applicable, to suspend or terminate a trial, including if
  participants are being exposed to unacceptable health risks or experiencing undesirable side effects or there are 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;
- inability to manufacture 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 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 product candidates, we may not be able to file such INDs on the timelines we expect. For example, we may experience manufacturing delays, including due to challenges associated with scaling up our manufacturing process, 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 such clinical trials. Additionally, even if 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 at which such trial is 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, delay our ability to obtain regulatory approval for such product candidate, 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, thereby impairing our ability to commercialize our product candidates, and may harm our business and resu

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 will rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials in compliance with current good clinical practices (cGCP) requirements; however, while we will enter into agreements governing their conduct, we will have limited influence over their actual performance. To the extent the CROs and clinical trial sites fail to enroll participants for our clinical trials, fail to conduct such clinical trials in accordance with cGCP, or experience significant delays in the execution of trials, including delays in achieving full enrollment, we may experience 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 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 we obtain it 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 our 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 are 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 product candidate may result in changes to the characteristics or behavior of the product candidate that could cause our product candidate to perform differently and affect the results of our ongoing clinical trials of such product candidate. 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. Similarly, 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 marketing approval, if obtained, the commercial profile of any approved label may be limited, or we may be subject to other significant negative consequences following marketing approval, if obtained.

Undesirable side effects that may be caused by our product candidates could cause us or regulatory authorities to interrupt, delay, or halt our 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 their side effects. Accordingly, we may observe unexpected side effects and/or higher levels of known side effects in clinical trials of our product candidates, including adverse events known in the same 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 such approved products 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 (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. We or our third-party manufacturers may encounter difficulties in production, which could delay or entirely halt our or 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. In July 2021, we entered into a long-term lease to establish and operate our own cGMP manufacturing facility to support our late-stage clinical development and early commercial product candidates across our product portfolio. However, we expect that it will take several years before we are able to begin manufacturing our product candidates at this facility, if at all. We currently 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 and we, once we begin to operate our manufacturing facility, 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 with respect to our product candidates 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 and effective and meet market demand.

Once we have completed the build-out of our manufacturing facility, we will be required to transition manufacturing processes and know-how of our product candidates from our contract manufacturers to our facility. Transferring manufacturing processes and know-how is complex and involves review and incorporation of both documented and undocumented processes that may have evolved over time. In addition, transferring production to our facility may require utilization of new or different processes to meet the requirements of our facility. Additional studies may also need to be conducted to support the transfer of certain manufacturing processes and process improvements. We cannot be certain that all relevant know-how and data has been adequately incorporated into the manufacturing process until the completion of studies and evaluations intended to demonstrate the comparability of material previously produced by our contract manufacturers with that generated by our facility.

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 we or 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 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. We or 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, consumables 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.

Additionally, due to global political, economic and other factors beyond our control, including the ongoing COVID-19 pandemic, there has been, and there may continue to be, a shortage of key materials and equipment that are necessary to manufacture our product candidates, including certain consumables such as bags, flasks and pipette tips. If we or our contract manufacturers are unable to obtain the materials and equipment necessary to manufacture our product candidates, we may experience delays in manufacturing our product candidates, which will harm our ability to conduct clinical trials and commercialize our product candidates in a timely manner or at all.

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 patients. 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 will reduce 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 are 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, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects or 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 therapeutic 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 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 cGCPs 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 (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. 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, in March 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. While the FDA has resumed certain on-site inspections of domestic manufacturing facilities, such activities are based on 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. In April 2021, the FDA issued additional guidance indicating that it plans to conduct voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites for situations in which in-person inspection would not be prioritized, deemed mission-critical or is otherwise limited by travel restrictions. 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 fraud and other misconduct committed by our personnel. 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, independent contractors, principal investigators, consultants, commercial partners, and vendors 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. Misconduct by our employees, independent contractors, principal investigators, consultants, commercial partners, and vendors 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 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 reg

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;
- 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 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. 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 (CRPA) 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 grant 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.

California voters approved the 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 are required 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.

Market opportunity and market growth may prove to be smaller than we estimated, 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 who are 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, and expect to continue to expect to 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 cGMP manufacturing facilities, nor do we have any in-house cGMP manufacturing capabilities. In July 2021, we entered into a long-term lease to establish and operate our own cGMP manufacturing facility to support our late-stage clinical development and early commercial product candidates across our product portfolio. Though we plan to begin building out this facility in the near future, we expect that it will take several years before we are able to begin manufacturing our product candidates at this facility, if at all. Until we are able to begin manufacturing our product candidates at our facility, we will rely on third-party contract manufacturers to manufacture our product candidates for preclinical and clinical testing. A limited number of third-party contract manufacturers specialize in or have the expertise required to manufacture our product candidates. Moreover, our contract manufacturers have limited capacity at their facilities and require commitments to secure availability well in advance of manufacturing any products. Additionally, we face competition from other biopharmaceutical companies to secure availability to manufacture our product candidates at these facilities. If the third-party contract manufacturers on which we rely to manufacture our product candidates do not have sufficient availability at their facilities to manufacture our product candidates in accordance with our timelines or are not otherwise able to meet our expected deadlines, we will experience delays in manufacturing our product candidates. In addition, our third-party contract manufacturers face intense competition to attract and retain qualified personnel. If our third-party contract manufacturers are unable to attract, retain, and motivate qualified personnel, they may be unable to perform their obligations in a timely manner, or their performance may be substandard or may not meet our quality requirements, which could cause us to experience delays in manufacturing our product candidates

In addition, 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 certain 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 contract 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 contract 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 contract manufacturers or we are unable to purchase these raw materials after regulatory approval

We rely, and expect to continue to rely, on third parties, including independent clinical investigators and CROs, to conduct or support 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 or support 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 cGCP 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 cGCPs through periodic inspections of trial sponsors, principal investigators, and trial sites. If we or any of our CROs fail to comply with applicable cGCPs, 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 cGCP 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 our CROs are unable to attract, retain, and motivate qualified personnel, they may be unable to perform their obligations in a timely manner, or their performance may be substandard. If independent investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if their performance is substandard or does not meet our quality requirements, 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 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 are 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 our rights to develop and commercialize our product candidates are subject to, in part, the terms and conditions of the licenses granted to us by such third parties. 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 those that we license 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. Moreover, we rely upon licenses to certain intellectual property rights and proprietary technology from third parties that are important or necessary to the development of our technology and products, including technology related to our manufacturing processes and our product candidates. These licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in all of our licenses. These licenses may also require us to grant back certain intellectual property rights to our licensors and to pay certain amounts relating to sublicensing patent and other 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 or at all. 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, 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, third parties from whom they license or have obtained the relevant patents, or any future licensees having rights to file, prosecute, maintain, and defend our patent rights fail, or have in the past failed, 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' or such third parties' 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, or third parties from whom they license or have obtained the relevant patents, 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

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 could determine that such a collaboration is 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 alterna

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 contractors 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 fed

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. In addition, we enter into agreements with our consultants, contractors, and outside scientific collaborators that 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

### 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 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 November 4, 2021 will expire on dates ranging from 2023 to 2040, subject to any patent extensions that may be available for such patents. If patents are issued on our patent applications pending as of November 4, 2021, the resulting patents are projected to expire on dates ranging from 2023 to 2042. 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 CROs, CDMOs, and other contractors and consultants as well as third party vendors of information technology and data security systems and services are vulnerable to damage and interruptions from security breaches, computer viruses, ransomware, 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 information technology 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. We also conducted

investigations to determine the extent to which our confidential information was accessed, lost, or stolen as a result of this cyberattack on SolarWinds and concluded that our confidential information was not materially accessed, lost, or stolen as a result of the cyberattack. We continue to monitor our systems and upgrade our security capabilities in order to mitigate risk. However, any access, loss, or theft of our confidential information in connection with a future cyberattack 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 to 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, require 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 continue to 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 September 30, 2021, our executive officers, directors, holders of 5% or more of our capital stock, and their respective affiliates owned approximately 64.5% of our outstanding voting stock. Therefore, these stockholders have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

### 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 September 30, 2021, 188.7 million shares of our 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 of 1933, as amended (Securities Act), unless held by our "affiliates" as defined in Rule 144 under the Securities Act. 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, as well as Rules 144 and 701 under the Securities Act. As of September 30, 2021, the holders of approximately 134.1 million shares of our common stock, or 71.1% of our outstanding shares, 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. Accordingly, these shares may be able to be sold in the public market upon issuance. In addition, in the future, we may issue additional shares of common stock, or other equity or debt securities convertible into common stock, in connection with a financing, acquisition, employee arrangement, or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause the price of our common stock to decline.

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 Securities Exchange Act of 1934, as amended (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 (CARES Act), our federal net operating losses (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 royalty 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, including the industrial space we lease on which we plan to build out and operate our manufacturing facility, are located in areas that have experienced significant natural disasters, including the San Francisco Bay Area and Seattle, Washington, each of which have experienced severe effects from wildfires and, in the case of the San Francisco Bay Area, 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.

In addition, if in the future a natural disaster, power outage, or other event occurred that prevented us from using all or a significant portion of our manufacturing facility, we may not be able to conduct our clinical trials or commercialize our products in accordance with our timelines or at all. 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 manufacturing facility or 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 was subject to a transition period until December 31, 2020 (the Transition Period), during which time EU rules continued to apply. Negotiations between the United Kingdom and the European Union 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, 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 is 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 expired), we have been required 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 associated with and may diminish our ability to protect our inventions and 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 (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 receives 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 of 2002 (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.

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.

As of June 30, 2021, the fair market value of our common stock held by non-affiliates exceeded \$700.0 million. Therefore, we will cease to be an emerging growth company as of December 31, 2021.

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 companies that comply with the new or revised accounting pronouncements as of public company effective dates.

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

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act (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 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 September 30, 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 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 <u>Number</u>	<u>Description</u>
3.1	Amended and Restated Certificate of Incorporation (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-39941), filed with the SEC on February 8, 2021).
3.2	Amended and Restated Bylaws (incorporated herein by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K (File No. 001-39941), filed with the SEC on February 8, 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 4.2 to the Company's Registration Statement on Form S-1(File No. 333-252061), filed with the SEC on January 28, 2021).
10.1*†	Option and License Agreement, effective October 15, 2021, by and between the Company and Beam Therapeutics Inc.
10.3(a)*#	2018 Equity Incentive Plan, as amended.
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.
- † Certain portions of this document that constitute confidential information have been redacted in accordance with Regulation S-K, Item 601(b)(10).
- # Indicates management contract or compensatory plan.
- 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.

SANA BIOTECHNOLOGY, INC.

Date: November 8, 2021	By:	/s/ Steven D. Harr, M.D.
Date. November 6, 2021	Бу	/s/ steven D. Han, M.D.
		Steven D. Harr, M.D.
		President and Chief Executive Officer
		(Principal Executive Officer)
Date: November 8, 2021	By:	/s/ Nathan Hardy
		Nathan Hardy
		Executive Vice President and Chief Financial Officer
		(Principal Financial and Accounting Officer)

# CERTAIN CONFIDENTIAL INFORMATION IN THIS DOCUMENT, MARKED BY [\*\*\*], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED

#### **OPTION AND LICENSE AGREEMENT**

This **OPTION AND LICENSE AGREEMENT** (this "**Agreement**") is made as of October 15, 2021 (the "**Effective Date**"), by and between **Beam Therapeutics Inc.**, a Delaware corporation having an office at 26 Landsdowne Street, Cambridge, MA 02139 ("**Beam**"), and **Sana Biotechnology, Inc.**, a Delaware corporation having an office at 188 E Blaine Street, #400, Seattle, WA 98102 ("**Sana**"). Sana and Beam are referred to in this Agreement individually as a "**Party**" and collectively as the "**Parties**".

#### RECITALS

WHEREAS, Sana is a biopharmaceutical company engaged in the development of novel cellular therapy products, with a focus on engineered T cell therapies for use in the treatment of various diseases;

WHEREAS, Beam is a biotechnology company focused on developing precision genetic medicines based on proprietary genome editing technologies; and

WHEREAS, Sana and Beam desire to enter into this Agreement for use of Beam's proprietary nuclease editing technology in connection with research and development of engineered cellular therapy products and, if successful, for Sana to further develop and commercialize such products, all under the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants contained herein, the receipt and sufficiency of which are hereby acknowledged, Sana and Beam hereby agree as follows:

# ARTICLE 1 DEFINITIONS

Unless the context otherwise requires, the terms in this Agreement with initial letters capitalized shall have the meanings set forth below, or the meaning as designated in the indicated places throughout this Agreement.

- **1.1** "Additional Selection Term" means the period starting on the Effective Date and ending on the one-year anniversary of the Effective Date.
- **1.2** "Additional PSC Product Type" means any Specified PSC Product Type that becomes an Additional PSC Product Type in accordance with <u>Section 3.1(b)</u>.
- **1.3** "**Affiliate**" means, with respect to any Person, any other Person that controls, is controlled by, or is under common control with, such Person. For purposes of this Agreement, a

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Person shall be deemed to control another Person if it owns or controls, directly or indirectly, at least fifty percent (50%) of the equity securities of such other Person entitled to vote in the election of directors (or, in the case that such other Person is not a corporation, for the election of the corresponding managing authority), or otherwise has the power to direct the management and policies of such other Person. The Parties acknowledge that in the case of certain entities organized under the laws of certain countries outside the United States, the maximum percentage ownership permitted by law for a foreign investor may be less than fifty percent (50%), and that in such case such lower percentage will be substituted in the preceding sentence, provided that such foreign investor has the power to direct the management and policies of such entity.

- **1.4** "Antigen Target" means [\*\*\*].
- **1.5** "Arising Cas12b Platform Inventions" means [\*\*\*] Inventions that are Conceived [\*\*\*] or [\*\*\*], which Inventions are: (a) compositions of Cas12b Platform Components; (b) methods of manufacturing [\*\*\*] Cas12b Platform Components; or (c) methods of use [\*\*\*] Cas12b Platform Components [\*\*\*].
- 1.6 "Arising Cas12b Platform Patents" means those Patent Rights filed on and Covering Arising Cas12b Platform Inventions.
- **1.7** "**Arising** [\*\*\*] **Inventions**" means [\*\*\*] Inventions that are Conceived [\*\*\*] or [\*\*\*], which Inventions are: (a) [\*\*\*]; and (b) are either (i) compositions [\*\*\*], (ii) methods of manufacturing [\*\*\*], or (iii) methods of use [\*\*\*].
  - **1.8** "**Arising** [\*\*\*] **Patents**" shall mean Patent Rights Covering Arising [\*\*\*] Inventions.
  - **1.9** "Base Editing" means [\*\*\*].
  - **1.10** "[\*\*\*] **Antigen Target**" means the [\*\*\*] antigen also known as [\*\*\*].
- **1.11 "Beam Patents"** means the Beam Platform Patents and the Beam Product Technology Patents. The Beam Patents as of the Effective Date are listed on **Exhibit A**.
- **1.12** "**Beam Platform Know-How**" means Know-How Controlled by Beam or its Affiliates that is: (a) actually disclosed, transferred or otherwise provided by Beam to Sana, including in connection with a Technology Transfer Plan; and (b) necessary or reasonably useful for (i) [\*\*\*].
- **1.13** "**Beam Platform Patents**" means any Patent Rights Controlled by Beam or its Affiliates as of the Effective Date or at any time during the Term that Cover: (a) [\*\*\*]; (b) [\*\*\*]; or (c) [\*\*\*].
  - **1.14** "Beam Platform Technology" means all Beam Platform Know-How and Beam Platform Patents.

- **1.15** "Beam Product Technology Patents" means any Patent Rights Controlled by Beam or its Affiliates as of the Effective Date or during the Term that are [\*\*\*]: (a) [\*\*\*]; (b) [\*\*\*]; or (c) [\*\*\*]; in each case ((a)-(c)) generated through Nuclease Editing using Beam Platform Technology or Cas12b Platform Components. For clarity, Beam Product Technology Patents exclude patents covering [\*\*\*].
- **1.16 "Beam Technology"** means, collectively, the Beam Platform Technology and the Beam Product Technology Patents.
- **1.17** "**BLA**" means (a) a Biologic License Application, as defined in the U.S. Public Health Service Act, as amended, and applicable regulations promulgated thereunder by the FDA, or (b) any equivalent or comparable application, registration or certification filed with a Regulatory Authority in any other country or region in the Territory.
- **1.18** "Blocked Antigen Target" means: (a) [\*\*\*]; and (b) any Antigen Target for which (i) Beam is bound by obligations (e.g., an exclusive license, option to enter into an exclusive license, or restrictive covenant) under a binding written agreement with a Third Party that is in conflict with, or would be breached, if such Antigen Target were to become an Additional CAR Antigen Target or a Replacement Antigen Target, (ii) such Antigen Target is expressly identified within [\*\*\*] that would result in the obligations described in subsection (b)(i) with respect to such Antigen Target, or (iii) Beam is conducting actual internal development activities directed at such Antigen Target, as evidenced by an approved budget of not less than \$[\*\*\*] or a relevant contract.
- **1.19** "Blocked Genetic Target" means: (a) [\*\*\*], and all [\*\*\*] Targets; and (b) any gene for which (i) Beam is bound by obligations (e.g., an exclusive license, option to enter into an exclusive license, or restrictive covenant) under a binding written agreement with a Third Party that is in conflict with, or would be breached, if such gene were to become a Genetic Target or (ii) such gene is expressly identified within [\*\*\*] that would result in the obligations described in subsection (b)(i) with respect to such Genetic Target.
- **1.20** "Blocked Product Type" means any Product Type for which (a) Beam is bound by obligations (e.g., an exclusive license, option to enter into an exclusive license, or restrictive covenant) under a binding written agreement with a Third Party that is in conflict with, or would be breached, if such Product Type were to become an Additional PSC Product Type or a Replacement PSC Product Type; (b) such Product Type is expressly identified within [\*\*\*] that would result in the obligations set forth in subsection (a) with respect to such Product Type; or (c) Beam is conducting actual internal development activities directed at such Product Type, as evidenced by an approved budget of not less than \$[\*\*\*] or a relevant contract.
- **1.21** "[\*\*\*] **Agreement**" means the license agreement dated [\*\*\*], by and between Blink Therapeutics Inc. and [\*\*\*] (the "[\*\*\*]"), as such agreement may be amended from time to time.
  - **1.22** "[\*\*\*] **Patent Rights**" means the Patent Rights licensed to Beam pursuant to the [\*\*\*] Agreement.

- **1.23** "Business Day" means a day other than a Saturday, Sunday, or holiday observed by the applicable Party responsible for the applicable obligation.
- **1.24** "Calendar Quarter" means each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1, except that the first Calendar Quarter of the Term shall commence on the Effective Date and end on the day immediately prior to the first to occur of January 1, April 1, July 1 or October 1 after the Effective Date, and the last Calendar Quarter shall end on the last day of the Term.
- **1.25** "Calendar Year" means each successive period of twelve (12) calendar months commencing on January 1 and ending on December 31, except that the first Calendar Year of the Term shall commence on the Effective Date and end on December 31 of the year in which the Effective Date occurs and the last Calendar Year of the Term shall commence on January 1 of the year in which the Term ends and end on the last day of the Term.
  - **1.26 "CAR"** means a chimeric antigen receptor.
- **1.27** "CAR Antigen Target" means: (a) a [\*\*\*] Antigen Target; (b) a [\*\*\*] Antigen Target; (c) a [\*\*\*] Antigen Target; and (d) up to [\*\*\*] Additional CAR Antigen Targets selected pursuant to Section 3.1(a); provided, however, that if any Replacement CAR Antigen Target is selected pursuant to Section 3.2 to replace any of the foregoing Antigen Targets, such Replacement CAR Antigen Target will become a CAR Antigen Target and the replaced Antigen Target will no longer be a CAR Antigen Target.
- **1.28** "CAR Products" means any therapeutic product that is or contains a human T cell that has been Edited and incorporates one or more CAR(s) that recognizes one or more CAR Antigen Targets, including any cell that is cultured or physically descended from any such Edited T cell; provided, however, that any such therapeutic product that recognizes any antigen target that is not a CAR Antigen Target is not a CAR Product.
- **1.29** "Cas12b Nuclease" means type-V CRISPR effectors Cas12b (formerly known as C2c1) that are enzymatically active, [\*\*\*].
- **1.30** "Cas12b Platform Components" means [\*\*\*]: (a) the Cas12b Nuclease; (b) Cas12b Nuclease guide RNAs; (c) [\*\*\*]; and/or (d) [\*\*\*].
  - **1.31** "[\*\*\*] **Antigen Target**" means the [\*\*\*] molecule or [\*\*\*].
  - **1.32** "[\*\*\*] **Antigen Target"** means the [\*\*\*] molecule also known as [\*\*\*] or [\*\*\*].
- **1.33** "cGMP" means current Good Manufacturing Practices as specified in the United States Code of Federal Regulations, ICH Guideline Q7A, or equivalent laws, rules, or regulations of an applicable Regulatory Authority at the time of manufacture.
- **1.34** "Change of Control" means, with respect to a Party, (a) a merger or consolidation of such Party with a Third Party that results in the voting securities of such Party outstanding immediately prior thereto, or any securities into which such voting securities have been converted

or exchanged, ceasing to represent at least fifty percent (50%) of the combined voting power of the surviving entity or the parent of the surviving entity immediately after such merger or consolidation, or (b) a transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the beneficial owner of fifty percent (50%) or more of the combined voting power of the outstanding securities of such Party, or (c) the sale or other transfer to a Third Party of all or substantially all of such Party's business.

- **1.35 "CMO"** means an entity or organization that provides contract manufacturing services.
- 1.36 "Commercially Reasonable Efforts" means, with respect to a Party, the efforts and resources typically used by biotechnology or pharmaceutical companies similar in size and scope to such Party to perform the obligation at issue, which efforts shall be substantially the same as those efforts commonly used by such Party with respect to other pharmaceutical products owned by it or to which it has rights, which product is at a similar stage of development or in a similar stage of product life, with similar developmental risk profiles, of similar market and commercial potential, taking into account the competitiveness of the marketplace, the proprietary position of the products, the regulatory structure involved, Regulatory Authority approved labeling, product profile, the profitability of the applicable products (including the amounts payable to licensors of Patent Rights and other intellectual property rights), issues of safety and efficacy, the likely timing of the product's entry into the market, the likelihood of receiving Marketing Approval and other relevant scientific, technical and commercial factors.
- **1.37 "Complement System Target"** means any protein that is part of the complement system or any gene that encodes for a protein within the complement system. The complement system is a [\*\*\*].
- **1.38** "Conceived" means: (a) with respect to Patent Rights, "invented" as defined under U.S. patent law, as evidenced by written documents of a Party; (b) with respect to copyrightable works, "authored" or "created" in accordance with U.S. copyright law; and (b) with respect to all other intellectual property, conceived, developed or reduced to practice. "Conception" has correlating meaning.
- **1.39** "Confidential Information" of a Party means all Know-How, unpublished patent applications and other non-public information and data of a financial, commercial, business, operational or technical nature (including information comprising or relating to concepts, discoveries, inventions, data, designs or formulae) that is disclosed by or on behalf of such Party or any of its Affiliates or otherwise made available to the other Party or any of its Affiliates, whether made available orally, in writing or in electronic form in connection with this Agreement. The terms and conditions of this Agreement shall constitute the Confidential Information of each Party. The Beam Technology shall constitute Beam's Confidential Information.
- **1.40** "Control" or "Controlled" means the possession of the ability to grant a license or sublicense of, or access to, Patent Rights, Know-How, or other tangible or intangible rights as provided for herein, other than pursuant to a license granted under this Agreement, without violating the terms of any agreement or arrangement with any Third Party. Notwithstanding

anything in this Agreement to the contrary, (a) Patent Rights under an applicable Third Party License shall not be Controlled by Beam except to the extent included in the rights licensed to Beam under this Agreement pursuant to the application of Section 2.4(b); and (b) a Party (or an Affiliate of a Party, as applicable) shall be deemed not to Control any Patent Rights or Know-How or such other rights that are owned or controlled by a Third Party described in the definition of "Change of Control" or such Third Party's Affiliates except to the extent such Patent Rights or Know-How or other rights: (i) arise from activities conducted by such Third Party or Affiliates under this Agreement after such Change of Control; or (ii) are developed or conceived by such Third Party or its Affiliates after such Change of Control using or incorporating the acquired Party's technology, including any improvements thereto.

- **1.41** "Cover" means, with respect to a particular subject matter at issue and a relevant Patent Right, that but for a license under such Patent Right (or ownership thereof), the composition, development, making, having made, use, sale, offer for sale, or importation of such subject matter by such Person would infringe one or more claim(s) included in such Patent Right or in the case of claims of Patent Rights under pending patent applications, would infringe (whether directly infringed or indirectly infringed by induced or contributory infringement) those claims of such Patent Rights if such claims were to issue. "Covering" and "Covered by" have correlating meanings.
- **1.42 CRO**" means an entity or organization that provides research and development services commonly outsourced on a contracted fee-for-service basis.
  - **1.43** "[\*\*\*] **Technology**" means any [\*\*\*].
  - **1.44 "Dollar"** means the U.S. dollar, and "\$" shall be interpreted accordingly.
- **1.45 "Editing"** means use of the Beam Platform Technology or Cas12b Platform Components for [\*\*\*]. "**Edit"** and "**Edited"** have a correlating meaning. "**Editing"** and its correlatives expressly exclude all Excluded Activities.
  - **1.46 "EMA"** means the European Medicines Agency or any successor entity thereto.
- **1.47 "Europe"** means the European Union and its member states as of the Effective Date and any member states added during the Term, and for the purposes of this Agreement, including the United Kingdom.
- **1.48** "Executive Officer" means (a) with respect to Beam, Beam's Chief Business Officer or their designee or (b) with respect to Sana, Sana's Chief Business Officer or their designee.
- **1.49** "Excluded Activities" means [\*\*\*] and any other method of editing genetic or cellular material other than Nuclease Editing.
  - **1.50 "Existing Third Party Licensor"** means any licensor of an Existing Third Party License.

- **1.51** "Existing Third Party Licenses" means any agreements entered into by Beam or its Affiliates with a Third Party prior to the Effective Date, including any amendments thereto as of the Effective Date, pursuant to which Beam or its Affiliates Controls any Beam Technology. All Existing Third Party Licenses are listed on **Exhibit B**.
  - **1.52 "FDA"** means the United States Food and Drug Administration or any successor entity thereto.
- **1.53 "Field"** means the diagnosis, treatment, prevention or palliation of any disease or condition in humans by administration of human cells Edited *ex vivo*; but excluding the following diseases: [\*\*\*].
- **1.54** "**First Commercial Sale**" means, with respect to a particular Licensed Product and country, the first sale in such country of such Licensed Product after Marketing Approval of such Licensed Product in such country.
- **1.55 "FPFD"** means, with respect to a clinical study and a Licensed Product, the first dose of such Licensed Product administered to the first patient in such clinical study.
- **1.56** "FTE" means the equivalent of a full time person, working for a minimum of [\*\*\*] hours per year, conducting activities under a Technology Transfer Plan, technology transfer activities, regulatory support activities, or other activities requested by Sana. In the case that any individual works partially on such activities under this Agreement and partially on other work in a given year, then the full-time equivalent to be attributed to such individual's work hereunder shall be equal to the percentage of such individual's total work time in such year that such individual spent working on such activities under this Agreement. In no event shall (a) any one individual be counted as more than one (1) FTE; or (b) indirect personnel (including support functions such as managerial, financial, legal or business development) constitute FTEs.
- **1.57** "FTE Rate" means an initial rate of [\*\*\*] per FTE per year. Commencing on [\*\*\*], the FTE Rate shall be changed annually to reflect any year-to-year percentage change in the Consumer Price Index for All Urban Consumers for the Boston-Cambridge-Newton Area, as published by the U.S. Department of Labor, Bureau of Labor Statistics ("CPI") (based on the change in the CPI from the most recent index available as of the Effective Date to the most recent index available as of the date of the calculation of such revised FTE Rate).
  - **1.58 "GAAP"** means the U.S. generally accepted accounting principles, consistently applied.
- **1.59** "GCP" means the then current good clinical trial standards for clinical trials for pharmaceuticals, as set forth in the United States Food, Drug and Cosmetic Act, as amended from time to time, or other applicable law, and such standards of good clinical practice as are required by the Regulatory Authorities of Europe and other organizations and Governmental Authorities in countries for which the applicable Licensed Product is intended to be developed, to the extent such standards are not less stringent than United States GCP.

- **1.60** "**Gene Editing**" means the prevention or treatment of human diseases by editing (including modifying or converting) or targeting DNA or RNA, either *ex vivo* for subsequent administration to a human of an organ, tissue, cell or subcellular component so edited or targeted, or in vivo by administering a product or product candidate to a human.
- **1.61** "Genetic Target" means, with respect to a particular Product Type, the genes selected by Sana as targets for Knock-In or Knock-Out targets for Nuclease Editing for such Product Type: (a) that are listed in  $Exhibit\ C$  or (b) that are selected in accordance with  $Exhibit\ C$  or (b) that are
- **1.62** "**Genetic Target Maximum**" means: (a) with respect to any PSC Product Type other than [\*\*\*], [\*\*\*] genes; and (b) with respect to [\*\*\*] as a PSC Product Type, [\*\*\*] genes.
- **1.63** "GLP" means the then-current good laboratory practice standards promulgated or endorsed by the FDA as defined in 21 C.F.R. Part 58, or comparable regulatory standards in jurisdictions outside the United States.
- **1.64** "Governmental Authority" means any national, international, federal, state, provincial or local government, or political subdivision thereof, or any multinational organization or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, any court or tribunal (or any department, bureau or division thereof, or any governmental arbitrator or arbitral body).
- **1.65 "Human Germline Modification"** means human germline modification, including intentionally modifying the DNA of human embryos or human reproductive cells.
- **1.66** "**IND**" means any investigational new drug application, clinical trial application, clinical trial exemption or similar or equivalent application or submission for approval to conduct human clinical investigations filed with or submitted to a Regulatory Authority in conformance with the requirements of such Regulatory Authority.
- **1.67** "**Ineligible**" means, with respect to a particular Antigen Target, gene or Product Type, that such Antigen Target, gene or Product Type is a Blocked Antigen Target, Blocked Genetic Target or Blocked Product Type (as applicable) at the time of receipt of the applicable Nomination Notice.
- **1.68 "Ineligibility Notice"** means a notice provided in accordance with Section 3.4 stating that an Antigen Target, gene or Product Type is Ineligible.
- **1.69** "**Invention**" means any information, including discoveries, improvements, modifications, processes, methods, assay, designs, protocols, formulas, data, inventions, know-how and trade secrets, patentable or otherwise, that is Conceived by or on behalf of a Party or its Affiliate or sublicensee pursuant to activities conducted in performance of obligations or exercise of rights and licenses under this Agreement or [\*\*\*] (including any [\*\*\*]), including all rights, title and interest in and to the intellectual property rights therein and thereto.

- **1.70** "[\*\*\*] **Sublicense**" means a sublicense granted by a Party to a Third Party that is [\*\*\*], including the [\*\*\*], as applicable. "[\*\*\*] Sublicensing" has a correlating meaning.
  - **1.71 "Knock-In"** means insertion of a certain gene (or portion of a gene) [\*\*\*] in the genome of a cell.
  - **1.72 "Knock-Out"** means [\*\*\*] in the genome of a cell.
- **1.73 "Knowledge"** means the actual knowledge of Beam's Chief Executive Officer, Chief Business Officer and Chief Legal Officer.
- **1.74** "**Know-How**" means any information, including discoveries, improvements, modifications, processes, methods, assays, designs, protocols, formulas, data, inventions, know-how and trade secrets (in each case, patentable, copyrightable or otherwise), and [\*\*\*] Materials (as defined [\*\*\*]) previously provided to Sana under [\*\*\*], but excluding any Patent Rights.
- **1.75** "**Law**" means any federal, state, local, foreign or multinational law, statute, standard, ordinance, code, rule, regulation, resolution or promulgation, or any order by any Governmental Authority, or any license, franchise, permit or similar right granted under any of the foregoing, or any similar provision having the force or effect of law.
- **1.76** "Licensed Product" means any CAR Product or PSC Product: (a) the making, using, selling, offering for sale, importing or exporting of which in the country in question is [\*\*\*] or (b) is [\*\*\*]. To clarify, two (2) or more Licensed Products will each be considered distinct Licensed Products if: (i) clinical trials for each are (or if an IND has not yet been filed, would be) conducted pursuant to separate IND filings or (ii) each obtains (or if a marketing approval has not yet been obtained, would obtain) marketing approval under separate NDAs.
  - **1.77** "**Major European Countries**" means France, Germany, Italy, Spain, and United Kingdom.
- **1.78** "Marketing Approval" means, with respect to a particular product, receipt of all regulatory clearances or approvals (which in the case of the EU may be through the centralized procedure) required in the jurisdiction of question for the sale of the applicable product in such jurisdiction, including receipt of Pricing Approval, if any, legally required for such sale.
- **1.79** "**Milestone Event**" means any Development Milestone Event and/or any Commercial Milestone Event, as applicable.
- **1.80** "**NDA**" means a New Drug Application filed with the FDA or an equivalent application to any Regulatory Authority (including a BLA, or its foreign equivalent) requesting Regulatory Approval for a new product.
- **1.81** "Net Sales" means the gross amount billed or invoiced by or on behalf of Sana, its Affiliates, and Sublicensees and any Affiliates of such Sublicensees (in each case, the "Invoicing Entity") or if not billed or invoiced the gross amount received by the Invoicing Entity, on sales, uses, leases or other transfers of Licensed Products, less the following to the extent applicable with

respect to such sales, leases or other transfers and not previously deducted from the gross invoice price:

- (a) customary trade, quantity or cash discounts to the extent actually allowed and taken (including discounts in the form of inventory management fees and chargebacks);
- **(b)** amounts actually repaid or credited by reason of rejection or return of any previously sold, leased or otherwise transferred Licensed Products;
  - (c) customer freight or insurance charges that are paid by or on behalf of the Invoicing Entity;
- (d) to the extent separately stated on purchase orders, invoices or other documents of sale, any sales, value added or similar taxes, custom duties or other similar governmental charges levied directly on the production, sale, transportation, delivery or use of a Licensed Product that are paid by or on behalf of the Invoicing Entity, but not including any tax levied with respect to income;
  - **(e)** rebates granted or given; and
  - **(f)** a reasonable allowance for uncollectible accounts; provided that:
- (i) in any transfers of Licensed Products between an Invoicing Entity and an Affiliate of such Invoicing Entity not for the purpose of resale by such Affiliate and not for use in a clinical study, charitable purposes, compassionate use or as free marketing samples provided in the customary course of the Invoicing Entity's business, Net Sales will be equal to the fair market value of the Licensed Products so transferred, assuming an arm's length transaction made in the ordinary course of business;
- (ii) if (A) an Invoicing Entity receives non-cash consideration for any Licensed Products, (B) an Invoicing Entity sells Licensed Product in a transaction not at arm's length with a non-Affiliate of an Invoicing Entity, or (C) any Licensed Product is sold by an Invoicing Entity at a discounted price that is substantially lower than the customary prices charged by Invoicing Entity, then Net Sales will be calculated based on the fair market value of such consideration or transaction, assuming an arm's length transaction made in the ordinary course of business, not to exceed the list price of the Licensed Products in any event; and
- (iii) with respect to any provision hereof requiring a calculation of fair market value, assuming an arm's length transaction made in the ordinary course of business, the Invoicing Entity may use the average price of the relevant Licensed Product sold for cash during the relevant period in the relevant country.

Transfers of Licensed Products by an Invoicing Entity to its Affiliate or a Sublicensee for resale by such Affiliate or Sublicensee or use in clinical studies, for compassionate use, or use as free marketing samples, will not be deemed Net Sales. Instead, if applicable, Net Sales will be determined based on the gross amount billed or invoiced by such Affiliate or Sublicensee upon resale of such Licensed Products to a Third Party purchaser. Transfers of Licensed Products by an

Invoicing Entity for use in clinical studies, for compassionate use, or use as free marketing samples will not be deemed Net Sales unless such Invoicing Entity bills or invoices for such Licensed Products, in which case, Net Sales will be determined based on the gross amount billed or invoiced by such Invoicing Entity upon transfer for such use.

If Sana enters into a Sublicense pursuant to which running royalties based on the net sales of a Licensed Product are payable to Sana and Sana is unable to incorporate into such Sublicense the Net Sales definition hereunder, then Sana may submit a request to Beam that the definition of net sales agreed upon in such Sublicense be deemed to apply to any amounts billed or invoiced by such Sublicensee under such Sublicense with respect to such Licensed Products. In addition to such proposal, Sana shall demonstrate to Beam's satisfaction, in Beam's sole discretion, that Beam would receive an amount of running royalties under such Sublicense applying such net sales definition equal to or greater than the amount of running royalties that Beam would otherwise receive under the definition of Net Sales hereunder. If Sana makes such demonstration to Beam's satisfaction, then the net sales definition under such Sublicense shall be deemed to apply to royalty payments on Licensed Products owed by Sana to Beam with respect to such Sublicensee.

- **1.82** "Nomination Notice" means either an Additional CAR Antigen Target Nomination Notice, Genetic Target Nomination Notice, Additional PSC Product Type Nomination Notice, or a Replacement Nomination Notice. Notwithstanding anything to the contrary in <u>Section 14.5</u>, each Nomination Notice shall be provided as set forth in <u>Section 14.5</u> and emailed to Beam's Alliance Manager to be effective.
- **1.83** "**Nuclease Editing**" means the process of utilizing a nuclease to induce double-strand breaks in DNA for [\*\*\*]. Nuclease Editing excludes [\*\*\*].
- 1.84 "Patent Challenge" means any direct, or indirect through the actions of another acting on Sana's, its Affiliate's, or a Sublicensee's behalf or upon its or their instruction, dispute or challenge, or any knowing, willful, or reckless assistance in the dispute or challenge by another, of the validity, patentability, scope, priority, construction, non-infringement, inventorship, ownership or enforceability of any Beam Patents or any [\*\*\*] Patent Rights or any claim thereof, or opposition or assistance in the opposition of the grant of any letters patent within the Beam Patents or [\*\*\*] Patent Rights, in any legal or administrative proceedings in a court of law, before the United States Patent and Trademark Office or other similar agency or tribunal in any jurisdiction, or in arbitration including by reexamination, *inter partes* review, opposition, interference, post-grant review, nullity proceeding, preissuance submission, third party submission, derivation proceeding or declaratory judgment action. For clarity, a Patent Challenge shall not include (a) arguments made by Sana that (i) distinguish the inventions claimed in patents or patent applications owned or controlled by Sana ("Sana Patents") from those claimed in the Beam Patents or [\*\*\*] Patent Rights but (ii) do not disparage the Beam Patents or [\*\*\*] Patent Rights or challenge the validity, scope, or enforceability of the Beam Patents' or [\*\*\*] Patent Rights' claims (excluding any claims that have been abandoned, lapsed, expired, or are otherwise no longer in force) under applicable patent laws, regulations or administrative rules, in each case (A) in the ordinary course of *ex* parte prosecution of the Sana Patents or (B) in inter partes proceedings before the United States Patent and Trademark Office or other agency or tribunal in any jurisdiction (excluding interferences or derivation proceedings), or in arbitration, wherein the

Sana Patents have been challenged; (b) arguments or assertions as to whether the Beam Patents or [\*\*\*] Patent Rights Cover a given product, to the extent arising in an action, claim or proceeding brought by Beam or by the [\*\*\*] or any Other Institution; (c) Sana payments of patent costs to another licensor or assignor of Sana Patents as required by the agreement under which the Sana obtained rights to such patent rights, even if the licensor or assignor is engaging in behavior or presenting arguments that would themselves be considered a Patent Challenge if done by Sana; nor (d) Sana being named as an essential party, real party in interest or other status similar to either of the foregoing, in an interference between the Beam Patents or [\*\*\*] Patent Rights and Sana Patents or other adversarial proceeding similar to an interference.

- **1.85 "Patent Rights"** means all patents and patent applications (which for the purpose of this Agreement shall be deemed to include certificates of invention and applications for certificates of invention), including all divisionals, continuations, substitutions, continuations-in-part, re-examinations, reissues, additions, renewals, revalidations, extensions, registrations and supplemental protection certificates and the like of any such patents and patent applications, and any and all foreign equivalents of the foregoing.
- **1.86 "Person"** means any individual, partnership, limited liability company, firm, corporation, association, trust, unincorporated organization, Governmental Authority, or other entity.
- **1.87 "Phase 1 Clinical Study"** means a clinical study in any country involving the initial introduction of an investigational new drug into humans, typically designed to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. In the United States, **"Phase 1 Clinical Study"** means a human clinical study that satisfies the requirements of 21 C.F.R. § 312.21(a).
- **1.88** "**Phase 2 Clinical Study**" means a human clinical study in any country conducted to evaluate the effectiveness of a drug for a particular indication or indications in patients with the disease or condition under study and, possibly, to determine the common short-term side effects and risks associated with the drug. In the United States, "**Phase 2 Clinical Study**" means a human clinical study that satisfies the requirements of 21 C.F.R. § 312.21 (b).
- **1.89 "Phase 3 Clinical Study"** means a human clinical study in any country, whether controlled or uncontrolled, that is performed after preliminary evidence suggesting effectiveness of the drug under evaluation has been obtained, and intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling. In the United States, "**Phase 3 Clinical Study**" means a human clinical study that satisfies the requirements of 21 C.F.R. § 312.21 (c).
- **1.90 "Pricing Approval"** means such governmental approval, agreement, determination or decision establishing prices for a Licensed Product that can be charged and/or reimbursed in regulatory jurisdictions where the applicable Governmental Authorities approve or determine the price and/or reimbursement of pharmaceutical products.

- **1.91 "Prime Editing"** means the process of utilizing [\*\*\*].
- **1.92 "Product Type"** means any type of cell.
- **1.93 "PSCs"** means induced pluripotent stem cells and embryonic stem cells.
- **1.94** "PSC Product" means any therapeutic product that is or contains an Edited cell of PSC Product Type(s), including any cell that is cultured or physically descended from any such Edited cell.
- **1.95** "**PSC Product Type**" means the following human cell types: (a) [\*\*\*] differentiated from PSCs; (b) [\*\*\*] differentiated from PSCs; and (c) if applicable, any Additional PSC Product Type selected pursuant to <u>Section 3.1(b)</u>; provided, however, that if a Replacement PSC Product Type is selected pursuant to <u>Section 3.2</u> to replace either of the foregoing PSC Product Types in subsection (a) or (b) above, such Replacement PSC Product Type will become a PSC Product Type, and the replaced PSC Product Type will no longer be a PSC Product Type.
- **1.96** "**Regulatory Authority**" means any applicable Governmental Authority responsible for granting INDs or Marketing Approvals for Licensed Products, including the FDA, EMA, and any corresponding national or regional regulatory authorities.
- 1.97 "Regulatory Exclusivity" means any exclusive marketing rights or data exclusivity rights conferred by any Regulatory Authority with respect to a biopharmaceutical product other than Patent Rights, including orphan drug exclusivity, new chemical entity exclusivity, data exclusivity, pediatric exclusivity, rights conferred in the United States under the Hatch-Waxman Act, the FDA Modernization Act of 1997 or the Biologics Price Competition and Innovation Act, or rights similar thereto outside the United States.
- **1.98** "Regulatory Materials" means any regulatory application, submission, notification, communication, correspondence, registration and other filings and submissions made to, received from or otherwise conducted with a Regulatory Authority in order to research, develop, manufacture, or commercialize a Licensed Product in a particular country or jurisdiction. "Regulatory Materials" include all INDs, BLAs, NDAs and Marketing Approvals.
- **1.99** "**Related Product**" means with respect to a Licensed Product (the "reference Licensed Product"), a Licensed Product targeting (a) the same Genetic Target and (b) (i) same splicing variant or mutation or (ii) a splicing variant or mutation whose alteration would have the same intended clinical outcome in the same intended patient population, in each case of clause (a), (b)(i) and (b)(ii) as the reference Licensed Product.
- **1.100** "Sana Technology" means all Know-How and Patent Rights that are (a) Controlled by Sana and its Affiliates as of the Effective Date or during the Term; (b) necessary or useful for Beam to perform its obligations under a Technology Transfer Plan; and (c) solely with respect to such Know-How, actually disclosed or otherwise provided by Sana to Beam in connection with a Technology Transfer Plan.

- **1.101** "Specified PSC Product Types" means: (a) [\*\*\*] cells differentiated from PSCs; and (b) [\*\*\*] cells differentiated from PSCs.
- **1.102** "**Subcontractor**" means a consultant, subcontractor, academic researcher or other vendors performing a Party's obligations under this Agreement on such Party's behalf.
- **1.103** "**Sublicense**" means any right (including any sublicense or covenant not to sue) granted by Sana or any Sublicensee to any Third Party, under or with respect to or permitting any use or exploitation of any of the Beam Patents or otherwise permitting the development, manufacture, marketing, distribution, use or sale of Licensed Products.
  - **1.104 "Sublicensee"** means any Person or entity granted a Sublicense.
  - **1.105** "**Territory**" means worldwide.
  - **1.106 "Third Party"** means any Person other than a Party or an Affiliate of a Party.
- **1.107 "Third Party Licenses"** means the Existing Third Party Licenses and any Third Party In-License that is deemed to be a Third Party License pursuant to <u>Section 2.4(b)</u>.
  - **1.108** "United States" or "U.S." means the United States of America, including its territories and possessions.
- 1.109 "Valid Claim" means: (a) a claim of an issued and unexpired patent within the Beam Patents that has not been (i) held permanently revoked, unenforceable, unpatentable or invalid by a decision of a court or governmental body of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, (ii) rendered unenforceable through disclaimer, or (iii) permanently lost through an interference or opposition proceeding without any right of appeal or review, or not appealed or put in for review within the applicable statutory or regulatory period; or (b) a pending claim of a pending patent application within the Patent Rights that has not been (i) abandoned or finally rejected without the possibility of appeal or refiling or (ii) pending more than [\*\*\*] years from the [\*\*\*] on such pending patent application, provided such patent application is not pending more than [\*\*\*] years from its earliest priority date. A pending claim that ceases to be a Valid Claim due to the foregoing time limit shall, if it later issues, qualify again as a Valid Claim, provided that it meets the requirements of clauses (a)(i)-(iii) of the foregoing definition.
  - **1.110 Interpretation.** In this Agreement, unless otherwise specified:
- (a) The words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation".
- **(b)** words denoting the singular shall include the plural and vice versa and words denoting any gender shall include all genders;
  - (c) the words "shall" and "will" have the same meaning;

- (d) references to any specific law, rule or regulation, or article, section or other division thereof, will be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof;
  - (e) references to "days" will mean calendar days, unless otherwise specified;
- **(f)** any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein);
- **(g)** words such as "herein", "hereof", and "hereunder" refer to this Agreement as a whole and not merely to the particular provision in which such words appear; and
- **(h)** the Exhibits and other attachments form part of the operative provision of this Agreement and references to "this Agreement" shall include references to the Exhibits and attachments.
- **1.111 Additional Definitions.** The following table identifies the location of definitions set forth in various Sections of the Agreement:

Definition	Section
Achieved Milestone	8.4(b)
Additional CAR Antigen Target	3.1(a)
Additional CAR Antigen Target Nomination Notice	3.1(a)
Additional Option Payment	<u>8.3</u>
Additional PSC Product Type Nomination Notice	3.1(b)
Alliance Manager	<u>4.1</u>
Applicable Patent Rights	9.1(h)
Assuming Party	<u>9.2(d)(ii)</u>
Beam Indemnitees	<u>13.2</u>
[***] Indemnitees	<u>13.3</u>
Beam Withholding Tax Action	<u>8.11(b)</u>
[***] Royalty Term	<u>8.7(a)</u>
[***]	9.1(c)(ii)(1)
Claims	<u>13.3</u>
Commercial Milestone Event	<u>8.5</u>
Confidentiality Agreement	<u>14.9</u>
CREATE Act	9.1(h)
Development Milestone Event	8.4
Disclosed Platform Know-How	<u>9.1(d)</u>
Disclosing Party	<u>10.1(a)</u>
Dispute	<u>14.6</u>

Employee-Initiated Solicitation	14.2
Enforcing Party	9.3(b)
Existing Employer	14.2
[***]	9.1(c)(ii)(2)
Genetic Target Nomination Notice	3.3
Genetic Target Selection Term	3.3
[***]	14.10
Indemnified Party	13.4
Indemnifying Party	13.4
Initial Technology Transfer Budget	<u>5.1</u>
Initial Technology Transfer Plan	5.1
Joint Inventions	<u>9.1(a)</u>
Jointly-Owned Inventions	<u>9.1(e)</u>
Jointly-Owned Patents	<u>9.1(f)</u>
Liabilities	<u>13.1</u>
[***]	<u>6.3</u>
[***]	<u>14.10</u>
New Genetic Target	<u>3.3</u>
Option Maximum	3.1(d)
Other Institutions	14.10
Prior MTA	14.9
Product Marks	9.6
Proposed Genetic Target	3.3
Prosecuting Party	<u>9.2(d)(ii)</u>
Prospective Employer	<u>14.2</u>
Receiving Party	<u>10.1(a)</u>
Relevant Enforcement Action	9.3(b)
Replacement CAR Antigen Target	<u>3.2</u>
Replacement Genetic Target	<u>3.3</u>
Replacement Nomination Notice	<u>3.2</u>
Replacement PSC Product Type	<u>3.2</u>
Replacement Selection Term	<u>3.2</u>
Royalty Information	8.7(d)
Royalty Term	<u>8.7(c)</u>
Sana Indemnitees	<u>13.1</u>
Sana Withholding Tax Action	<u>8.11(c)</u>
SEC	<u>10.5(b)</u>
Skipped Milestone	<u>8.4(b)</u>
Sole Inventions	9.1(a)

Soliciting Employee	<u>14.2</u>
Technology Transfer Budget	<u>5.1</u>
Technology Transfer Plan	<u>5.1</u>
Term	<u>11.1</u>
Third Party In-Licenses	2.4(b)

## ARTICLE 2 LICENSES

#### 2.1 Licenses to Sana.

- (a) Beam Platform Technology. Beam hereby grants to Sana a non-exclusive, non-transferable (except in accordance with Section 14.3), royalty-bearing license, with the right to grant sublicenses solely as provided in Section 2.1(c), under the Beam Platform Technology: (i) manufacture and have manufactured the Cas12b Platform Components; and (ii) use the Cas12b Platform Components to perform Nuclease Editing; in each case of (i) and (ii) solely for the purpose of researching or developing Licensed Products in the Territory solely for use in the Field.
- **(b) Beam Product Technology Patents.** Beam hereby grants to Sana a non-exclusive, non-transferable (except in accordance with <u>Section 14.3</u>), royalty-bearing license, with the right to grant sublicenses solely as provided in <u>Section 2.1(c)</u>, (i) under the Beam Product Technology Patents, to research, develop, make, have made, use, sell, offer for sale, import, commercialize or otherwise exploit Licensed Products in the Territory solely for use in the Field; and (ii) under the Beam Platform Technology, as necessary to manufacture Licensed Products in the Territory solely for use in the Field.

#### (c) Sublicenses.

(i) Subject to the terms and conditions of this Agreement and the applicable Third Party Licenses, Sana may grant a sublicense: (A) under the license granted by Beam to Sana in Section 2.1(a), to Sana's CROs, CMOs and Subcontractors solely for purposes researching and developing Licensed Products on behalf of Sana or its Affiliates in the Field in the Territory; (B) under the license granted by Beam to Sana in Section 2.1(b), to one or more Affiliates or Third Parties solely for purposes of development, manufacture and commercialization of one or more Licensed Products (through one or more (but not to exceed [\*\*\*]) tiers); and (C) under the license(s) granted by Beam to Sana under Section 2.1(a) and/or Section 2.1(b), for purposes other than as described in the foregoing clause (A) or (B), to one or more Affiliates or Third Parties subject to Beam's prior written consent. Sana shall remain responsible for the performance of all of its Affiliates, Sublicensees, CMOs, CROs and Subcontractors to the same extent as if such activities were conducted by Sana, and shall remain responsible for any payments due hereunder with respect to activities of any of its Affiliates or Sublicensees. In any agreement entered into by Sana with an Affiliate, Sublicensee, CRO, CMO or Subcontractor that grants rights to such Sublicensee, CRO, CMO or Subcontractor under any [\*\*\*] Patent Rights sublicensed to Sana pursuant to this Agreement, Sana shall ensure that each such agreement includes (A) the requirement that such Affiliate, Sublicensee, CRO, CMO or Subcontractor complies with the

provisions set forth on **Exhibit D**, and (B) all other provisions set forth in Section 2.3 (with respect to Affiliates) or Section 2.4 (with respect to Sublicensees, CROs, CMOs and Subcontractors) of the [\*\*\*] Agreement, as applicable to such Affiliate, Sublicensee, CRO, CMO or Subcontractor.

- (ii) Sana shall provide Beam with a copy of each executed Sublicensee agreement promptly after execution thereof (but in any event within [\*\*\*]), which shall be treated by Beam as Sana's Confidential Information, provided that (A) Sana shall have no obligation to provide Beam with a copy of any agreement between Sana or a Sublicensee, on the one hand, and an Affiliate of Sana or such Sublicensee, or any agreement with a CRO or CMO (solely for the provision of research or services for or on behalf of Sana or its Affiliates), and (B) with respect to any Sublicensee agreement that includes a sublicensee under a Third Party License that requires Beam to provide the applicable Third Party licensor a copy of any such Sublicensee agreement or a summary of the terms of such Sublicensee agreement, Beam shall be permitted to provide such Third Party licensor with such copy or summary in accordance with Section 10.3(c). Prior to providing a copy of such Sublicensee agreement to Beam, Sana may, except to the extent otherwise required under any Third Party License, redact certain terms of any such Sublicensee agreement to the extent not pertinent to an understanding of a Party's obligations or benefits under this Agreement or a verification of compliance with the requirements of this Agreement.
- **(iii)** Each agreement in which Sana grants a sublicense hereunder shall be subject to the applicable terms and conditions of this Agreement and shall expressly include the terms set forth in **Exhibit D** with respect to each Third Party License sublicensed to the Affiliate, Sublicensee, CRO or Subcontractor, as applicable.
- (iv) Solely to the extent that Sana, its Affiliate or Sublicensee is permitted to grant a sublicense under this <u>Section 2.1</u> and has the right to grant further sublicenses, if Sana, such Affiliate or such Sublicensee cannot grant such further sublicenses under a particular Third Party License, then at Sana's request in conjunction with Sana's granting of a sublicense under this <u>Section 2.1(c)</u>, or its Affiliate or Sublicensee's granting of a further sublicense, Beam shall not unreasonably refuse to grant a sublicense under such Third Party License to such Affiliate or Sublicensee (or further Sublicensee) for no additional consideration to Beam and otherwise on terms that are consistent with the Third Party License, the sublicense granted by Sana to its Affiliate or such Sublicensee, and the terms of this Agreement.
- **(d) Retained Rights.** Notwithstanding the licenses granted by Beam to Sana in this <u>Section 2.1</u>, Sana acknowledges and agrees to the Institutions' (as defined in the [\*\*\*] Agreement) reserved rights and the restrictions set forth in Section 2.2 of the [\*\*\*] Agreement. Additionally, notwithstanding anything to the contrary set forth in this Agreement, Sana acknowledges and agrees that the licenses granted to Sana under this <u>Section 2.1</u> expressly exclude any right to engage in any Excluded Activities.
- **(e)** [\*\*\*] **Agreement**. Without limitation, Sana expressly understands and agrees that, the rights and licenses granted under this Agreement (insofar as they relate to a sublicense of the [\*\*\*] Patent Rights) are subject to, and Sana will comply, and will cause its Affiliates, Sublicensees, Subcontractors and CROs to comply with, all applicable terms and conditions of the [\*\*\*] Agreement, whether or not expressly stated in this Agreement or any

Exhibit. Sana represents and warrants that it has received on [\*\*\*], a redacted copy of the [\*\*\*] Agreement, and has reviewed such copy of the [\*\*\*] Agreement. In the event of a conflict between this Agreement (including any Exhibits) and the [\*\*\*] Agreement, the [\*\*\*] Agreement shall control.

- **2.2 License to Beam.** Subject to the terms and conditions of this Agreement, Sana hereby grants to Beam a royalty-free, non-exclusive license, with the right to grant sublicenses only to its Affiliates and Subcontractors (subject to Section 2.5), under the Sana Technology, solely to conduct those research activities allocated to Beam in the Technology Transfer Plan.
- **2.3 No Implied Licenses; Negative Covenant.** Except as expressly set forth herein, neither Party shall acquire any license or other intellectual property interest, by implication or otherwise, under or to any Patent Rights, Know-How, or other intellectual property Controlled by the other Party, or in the case of Sana, as to any technology, intellectual property rights, products or biological materials of the any Institute (as defined in the [\*\*\*] Agreement), or any other entity, regardless of whether such technology, intellectual property rights, products or biological materials are dominant, subordinate or otherwise related to any [\*\*\*] Patent Rights. Sana hereby covenants and agrees that it will not, and will not permit any Affiliate or Sublicensee to, use the Beam Patents for (a) Human Germline Modification, (b) the stimulation of biased inheritance of particular genes or traits within a population of plants or animals, or (c) for modifying the tobacco plant (including any plant part, plant cell, plant tissue or plant seed), except for modifications that (i) are related to the use of the tobacco plant as a manufacturing system or as a model system for research purposes but (ii) are not related to any use or application in the cultivation, growth, manufacture, exportation or production of any tobacco product.

### 2.4 Third Party Licenses.

- (a) **Terms of Third Party Licenses**. Sana acknowledges that the licenses granted to Sana in <u>Section 2.1</u> include sublicenses under certain Beam Technology that is licensed to Beam pursuant to Third Party Licenses (i) set forth on **Exhibit B**, in the case of Existing Third Party Licenses, or (ii) disclosed to Sana in accordance with <u>Section 2.4(b)</u> in the case of other Third Party Licenses. Sana also acknowledges that the licenses granted to Sana in <u>Section 2.1</u> are subject to, and that Sana will comply with, the terms of the Existing Third Party Licenses as set forth on **Exhibit D**.
- **(b)** Additional Third Party Licenses. If Beam or any of its Affiliates enters into any agreement with a Third Party after the Effective Date pursuant to which it obtains a license from such Third Party or acquires any Patent Rights that would, absent any restriction relating to Patent Rights in-licensed or acquired after the Effective Date, fall within the definition of Beam Technology (including any amendment to a Third Party License to add rights to any such additional Patent Rights) ("Third Party In-Licenses"), then Beam shall provide Sana with written notice [\*\*\*]. For clarity, any such provided [\*\*\*]. Any Third Party In-License for which Beam is required to provide Sana notice under this Section 2.4(b) shall be [\*\*\*]. If no such notice is provided within [\*\*\*] after Sana's receipt of disclosure notice with respect to the Third Party In-License, then the [\*\*\*]. In the event that [\*\*\*].

**2.5 Subcontractors.** Each Party may engage Subcontractors to perform any activities assigned to it under the Technology Transfer Plan or otherwise under this Agreement. Each contract between a Party and a Subcontractor shall be consistent with the provisions of this Agreement (including Section 2.1(c)), and shall include provisions that enable the subcontracting Party to comply with all its obligations under this Agreement as though such Party had performed the contracted work itself. Each Party shall be responsible for the management of its Subcontractors and shall remain directly responsible for its obligations to conduct the activities assigned to it under the Technology Transfer Plan or otherwise under this Agreement that have been delegated or Subcontracted to any Subcontractor, and shall be directly responsible for the performance of its Subcontractors.

## ARTICLE 3 ADDITIONS; SUBSTITUTIONS

### 3.1 Option for Additional CAR Antigen Targets and Additional PSC Product Types.

- (a) Option for Additional CAR Antigen Targets. During the Additional Selection Term and subject to the Option Maximum as defined in and in accordance with Section 3.1(d), Sana shall have the option to select, at Sana's discretion and by submission of a nomination notice to Beam (each, an "Additional CAR Antigen Target Nomination Notice"), up to [\*\*\*] single Antigen Targets as nominated Additional CAR Antigen Targets under this Agreement. Each Additional CAR Antigen Target Nomination Notice shall include the GenBank reference number for each nominated Antigen Target. Unless Beam provides an Ineligibility Notice with respect to any nominated Antigen Target, such Antigen Target nominated by Sana under an Additional CAR Antigen Target Nomination Notice shall automatically be deemed eligible to be an "Additional CAR Antigen Target" under this Agreement (up to the Option Maximum), and will become an Additional CAR Antigen Target upon timely payment of the Additional Option Payment. If the Additional Option Payment is not timely paid, then the selected Antigen Target will not become an Additional CAR Antigen Target.
- **(b) Option for Additional PSC Product Types.** During the Additional Selection Term and subject to the Option Maximum as defined in and in accordance with Section 3.1(d), Sana shall have the option to select, at Sana's discretion and by submission of a nomination notice to Beam (each, "Additional PSC Product Type Nomination Notice") any Specified PSC Product Type as an Additional PSC Product Type under this Agreement. Unless Beam provides an Ineligibility Notice, the Specified PSC Product Type shall automatically be deemed eligible to be an Additional PSC Product Type under this Agreement (up to the Option Maximum), and will become an Additional PSC Product Type upon timely payment of the Additional Option Payment. If the Additional Option Payment is not timely paid, then the selected Specified PSC Product Type will not become an Additional PSC Product Type.
- **(c) Effect of Ineligibility Notice**. If Beam provides a Ineligibility Notice under subsection (a) or (b) above, then, notwithstanding the expiration of the Additional Selection Term prior to Sana's successful nominations up to the Option Maximum, Sana shall, at a minimum, have an additional [\*\*\*] days to select (i) an alternative Antigen Target as a nominated Additional CAR

Antigen Target or (ii) an alternative Specified PSC Product Type as a nominated Additional PSC Product Type; in each case subject to the limitations in Section 3.1(a) or 3.1(b) (and so on until any such selected Antigen Target becomes an Additional CAR Antigen Target or any Specified PSC Product Type becomes an Additional PSC Product Type, as applicable), provided, however that in no event shall Sana have greater than [\*\*\*] months after the expiration of the Additional Selection Term for the nomination described in the foregoing (i) or (ii).

- **(d) Option Maximum.** Sana shall have the right to add a maximum of [\*\*\*] Additional CAR Antigen Targets and/or Additional PSC Product Types in the aggregate under this Agreement during the Additional Selection Term, as may be extended as described in <u>Section 3.1(c)</u> (the "**Option Maximum**"). The Option Maximum can be reached only by either (i) the addition of [\*\*\*] Additional CAR Antigen Targets, (ii) the addition of [\*\*\*] Additional CAR Antigen Target and [\*\*\*] Additional PSC Product Type, or (iii) the addition of [\*\*\*] Additional PSC Product Types.
- **(e) Payment of Additional Option Payment.** Upon any Antigen Target nominated by Sana pursuant to Section 3.1(a) being selected as an Additional CAR Antigen Target and upon any Specified PSC Product Type being selected as an Additional PSC Product Type, Sana shall pay the Additional Option Payment for such Additional CAR Antigen Target or Additional PSC Product Type, as applicable, in accordance with Section 8.3.
- 3.2 Replacement CAR Antigen Target or Replacement PSC Product Type. At any time after the Effective Date, and prior to the third anniversary of the Effective Date (the "Replacement Selection Term"), Sana shall have the right to select, at Sana's discretion and by submission of a nomination notice to Beam (each, a "Replacement Nomination Notice"), either (a) a single Antigen Target as a replacement for one of the CAR Antigen Targets or (b) if not previously selected as pursuant to Section 3.1(b), any Specified PSC Product Type as a replacement for one of the PSC Product Types specified in subsection (a) or (b) of the definition of PSC Product Types. Sana may submit a Replacement Nomination Notice up to [\*\*\*] times per year, provided, however that (A) in the event Beam provides an Ineligibility Notice, Sana may submit additional Replacement Nomination Notices during the applicable year with respect to any applicable Antigen Target which is a Blocked Antigen Target; and (B) any Replacement Nomination Notice may contain multiple single Antigen Target candidates for a Replacement CAR Antigen Target, specifying order of preference. Each Replacement Nomination Notice with respect to a proposed Replacement CAR Antigen Target shall include the GenBank reference number for such Antigen Target and shall specify the CAR Antigen Target that will be replaced if such Antigen Target is deemed a Replacement CAR Antigen Target as set forth herein. With respect to Antigen Targets candidates, the first-preference (as specified in the Replacement Nomination Notice) Antigen Target which is not a Blocked Antigen Target nominated by Sana under a Replacement Nomination Notice shall automatically be deemed a "Replacement CAR Antigen Target" or a "Replacement PSC Product Type", as applicable, under this Agreement unless Beam provides a Non-Availability notice to Sana in accordance with Section 3.4. If all Antigen Targets selected by Sana under such Replacement Nomination Notice fail to become a Replacement CAR Antigen Target because it/they is/are a Blocked Antigen Target, then, notwithstanding the expiration of the Replacement Selection Term Sana shall have an additional [\*\*\*] to select an alternative Antigen Target as a nominated Replacement CAR Antigen Target

(and such process may be repeated until any such selected Antigen Target becomes a Replacement CAR Antigen Target), provided, however that in no event shall Sana have greater than [\*\*\*] after the expiration of the Replacement Selection Term for the nomination described in the foregoing (i) or (ii). Effective upon: (x) any Antigen Target being deemed a Replacement CAR Antigen Target, such Replacement CAR Antigen Target shall be deemed a CAR Antigen Target and the replaced CAR Antigen Target shall no longer be deemed a CAR Antigen Target; and (y) any Specified PSC Product Type being deemed a Replacement PSC Product Type, such Specified PSC Product Type shall be deemed a PSC Product Type and the replaced PSC Product Type shall no longer be deemed a PSC Product Type. Sana shall only have the right to designate [\*\*\*] Replacement CAR Antigen Target or [\*\*\*] Replacement PSC Product Type under this Agreement.

- 3.3 **Genetic Target Nominations.** At any time after the Effective Date, and prior to the third anniversary of the Effective Date (the "Genetic Target Selection Term"), Sana shall have the right to select for each Product Type, at Sana's discretion and by submission of a nomination notice to Beam (each, a "Genetic Target Nomination Notice"), either: (a) a new proposed Genetic Target (a "New Genetic Target"); or (b) a proposed Genetic Target as a replacement for one of the previously selected Genetic Targets (a "Replacement Genetic Target"); in each case ((a) and (b)) provided that (i) the Genetic Target Nomination Notice may only be delivered [\*\*\*] per Calendar Quarter unless the Genetic Target Selection Term is deemed extended as described below, in which case Sana may provide a Genetic Target Nomination Notice up to [\*\*\*] every calendar month during any such deemed extension; and (ii) Sana shall not submit any Genetic Target Nomination Notice which could result in a total number of Genetic Targets for any Product Type being greater than the Genetic Target Maximum. Each Genetic Target Nomination Notice shall specify the Product Type for which it applies, and include the GenBank reference number for such New Genetic Target or Replacement Genetic Target, as applicable (the "Proposed Genetic Target") and, with respect to Replacement Genetic Targets, shall specify the Genetic Target that will be replaced if such Proposed Genetic Target is deemed a Genetic Target as set forth herein. Each Proposed Genetic Target nominated by Sana under a Genetic Target Nomination Notice shall automatically be deemed a Genetic Target under this Agreement unless Beam provides an Ineligibility Notice therefor. If Beam provides a Ineligibility Notice, then notwithstanding the expiration of the Genetic Target Selection Term due to Sana's submitted proposed Genetic Target(s) being Blocked Genetic Target(s), Sana shall, at a minimum, have an additional [\*\*\*] to select an alternative Proposed Genetic Target for the applicable Product Type (and such process may be repeated until any such Proposed Genetic Target becomes a Genetic Target), provided, however that in no event shall Sana have greater than [\*\*\*] months after the expiration of the Genetic Target Selection Term for the nomination described in the foregoing (i) or (ii). Effective upon any Replacement Genetic Target being deemed a Genetic Target for any Product Type, the replaced Genetic Target shall no longer be deemed a Genetic Target for such Product Type.
- **3.4 Blocked Antigen Targets, Blocked Genetic Targets, or Blocked Product Types**. Within [\*\*\*] Business Days after Beam's receipt of a Nomination Notice submitted in accordance with the terms of this Agreement, Beam shall notify Sana in writing confirming whether or not such Antigen Target is a Blocked Antigen Target, whether or not such Genetic Target is a Blocked Genetic Target, or whether or not a Specified PSC Product Type is a Blocked Product Type. If at any time during the Additional Selection Term (or any extended time period for selection as set

forth on Section 3.1(a) or Section 3.1(b)), or during the Genetic Target Selection Term, or during the Replacement Selection Term (or any extended time period for selection as set forth on Section 3.2), any Ineligibility that precluded Beam from selecting as an Additional CAR Antigen Target, Proposed Genetic Target, Additional PSC Product Type or Replacement CAR Antigen Target, as applicable, an Antigen Target, Genetic Target or Product Type that Sana previously nominated under a Nomination Notice later expires, terminates or is otherwise modified such that such proposed Antigen Target would no longer be a Blocked Antigen Target, such Proposed Genetic Target would no longer be a Blocked Product Type, as applicable, then Beam will promptly notify Sana of such expiration, termination or modification (as applicable).

## ARTICLE 4 COMMUNICATION

**4.1 Alliance Managers.** Promptly following the Effective Date, each Party shall designate an individual to serve as the main point of contact for each Party for the activities under this Agreement to exchange information, facilitate communication and coordinate the Parties' activities hereunder (each, an "**Alliance Manager**"). Each Party may change its designated Alliance Manager from time to time upon written notice to the other Party.

## ARTICLE 5 TECHNOLOGY TRANSFER

- 5.1 Initial Technology Transfer. Within [\*\*\*] Business Days following the Effective Date, Beam shall, at no additional cost to Sana, provide a technology transfer to Sana or its designee of (a) the [\*\*\*], (b) [\*\*\*] described or specified in or generated under the Technology Transfer Plan; and (c) the other information and assistance specifically described in Exhibit E (the "Initial Technology Transfer Plan"). [\*\*\*] shall be responsible for the internal and out-of-pocket costs incurred in connection with Initial Technology Transfer Plan in accordance with the budget (the "Initial Technology Transfer Budget") set forth in Exhibit E. In addition, the Parties may from time to time agree in writing certain other technology transfer activities. Any such activities will be set forth in a written plan (each such plan, including the Initial Technology Transfer Plan, a "Technology Transfer Plan") that includes the timeline and details of all technology transfer activities to be conducted thereunder. In addition, with respect to each Technology Transfer Plan, the Parties will agree in writing in advance upon a mutually agreed budget [\*\*\*] incurred in connection with any such Technology Transfer Plan (each such budget, including the Initial Technology Transfer Budget, a "Technology Transfer Budget").
- **5.2 Technology Transfer Cost.** Sana shall be responsible to reimburse Beam for internal costs (at the thencurrent FTE Rate) and out-of-pocket costs incurred in performance of any Technology Transfer Plan incurred in accordance with the applicable Technology Transfer Budget and Section 8.2, with the exception of [\*\*\*]. Sana shall be responsible for all costs Sana or its Affiliates incur with respect to activities assigned to it under any Technology Transfer Plan.
- **5.3 Performance.** Each Party shall carry out the activities assigned to it under the Technology Transfer Plan in accordance with the timeline therefor contemplated by the

Technology Transfer Plan and shall conduct such activities in good scientific manner, in compliance with all applicable Laws in all material respects, including where applicable, cGMP, GLP and GCP.

# ARTICLE 6 DEVELOPMENT AND REGULATORY; COMMERCIALIZATION

- **6.1 General.** Subject to the terms and conditions of this Agreement, as between the Parties, Sana will be solely responsible for the development of each Licensed Product in the Field after the completion of the applicable Technology Transfer Plan, at Sana's sole cost and expense.
- **6.2 Development Costs**. Sana shall be solely responsible for all costs and expenses incurred in the development of the Licensed Products under this Agreement.
- **Reports.** Within [\*\*\*] days after the end of each Calendar Year, Sana shall provide Beam with a written report summarizing at a high level, all material development and commercialization activities performed by or on behalf of Sana, its Affiliates and Sublicensees for the Licensed Products in the Field since the last report, including: (a) research and development activities, including information regarding the status of specific Licensed Products in development and their therapeutic applications, including [\*\*\*] Licensed Products being developed or commercialized; (b) the status of applications for Marketing Approvals, a summary of [\*\*\*] (however, Sana will not be required to disclose any confidential or proprietary information related thereto that is not related to the Cas12b Platform Components); (c) commercialization or other distribution activities; and (d) marketing activities. Together with each report, Sana shall provide Beam with a copy of the then current development plan, which shall include sufficient detail to enable Beam to assess what Licensed Products are in development and the status of such development. In addition to Sana's obligations under Section 6.3, Sana shall provide any [\*\*\*] to Beam within a reasonably prompt period to allow for a reasonable opportunity for Beam to review and comment thereon, such period not to exceed [\*\*\*] Business Days after the date of Sana's receipt, unless the foregoing report is due prior to the expiration of such [\*\*\*] day period.
- **6.4 Cooperation.** Sana and Beam recognize that common reagents, and common manufacturing process steps may be used in the manufacturing of both Licensed Products and Beam's (or Beam's Affiliates, licensees or sublicensees) products or compounds utilizing Cas12b Platform Components. To the extent that a Regulatory Authority requires Sana and Beam to share information regarding the use of such reagents and processes, the Parties will work in good faith to provide the information reasonably necessary to facilitate compliance with such Regulatory Authority requirement, and Beam shall use good faith efforts to obtain and share with Sana such information obtained from its Affiliates and Third Party licensees and sublicensees under the Beam Technology in connection with products or compounds utilizing the same Cas12b Platform Components as the Licensed Products. Sana agrees that Beam will have the right to share with such Affiliates and Third Parties any information provided by Sana under this Section 6.4.

### 6.5 Regulatory Strategies and Responsibilities.

- (a) Sana shall be solely responsible for all regulatory affairs for the Licensed Products in the Field, including the preparation and filing of the IND, NDA and other Regulatory Materials for the Licensed Products in the Field, at its sole expense.
- **(b)** Sana shall provide Beam with notice of all IND, BLA, or NDA submissions with any Regulatory Authorities in the Territory regarding the Licensed Products in a timely manner after submission thereof.
- **6.6 Meetings with Regulatory Authorities**. At Sana's request and Beam's agreement (not to be unreasonably withheld), Beam shall provide reasonable assistance to Sana in preparation for any in-person meeting or teleconference with a Regulatory Authority (or related advisory committees) or other request of a Regulatory Authority, in each case to the extent such assistance is reasonably required in order for Sana to seek or obtain Marketing Approval for Licensed Products, and provided that Beam will not be required to provide any Beam Confidential Information or Know-How beyond what is agreed pursuant to a Technology Transfer Plan. In the event that Beam agrees to provide any such assistance, Sana shall reimburse Beam, in accordance with Section 8.2, for those documented and agreed upon costs and expenses incurred by Beam in connection with conducting such activities.
- **6.7 Commercialization.** Subject to the terms and conditions of this Agreement, as between the Parties, Sana shall be solely responsible, at its sole cost and expense, for commercialization of Licensed Products in the Field in the Territory.

## ARTICLE 7 MANUFACTURING

**7.1 Manufacturing Technology Transfer**. Beam will notify Sana in the event that it establishes (in Beam's sole discretion) a cGMP compliant manufacturing process for the Cas12b Platform Components licensed to Sana under <u>Section 2.1(a)</u>. In such event, Sana may request that (b) Beam to transfer such process to Sana for Sana's use in connection with the exercise of the rights granted to it under this Agreement or (b) facilitate an introduction to Beam's current Third Party manufacturers for Cas12b Platform Components and permit such Third Party manufacturer(s) to manufacture such Cas12b Platform Components for Sana. In the event that Sana requests to transfer such process, the Parties will use good faith efforts to endeavor to negotiate and agree upon a manufacturing transfer plan and a budget to reimburse Beam for its internal costs (at the then-current FTE Rate) and out-of-pocket costs incurred in connection with any such transfer in accordance with <u>Section 8.2</u>. Beam will not be required to provide any manufacturing transfer unless and until the Parties agree upon such plan and budget.

## ARTICLE 8 FINANCIAL PROVISIONS

**8.1 Upfront Payment.** Within [\*\*\*] Business Days after the Effective Date, Sana shall pay to Beam a one-time, non-refundable, non-creditable upfront payment of fifty million Dollars

(\$50,000,000). The Parties acknowledge and agree that [\*\*\*] of the foregoing upfront payment is in consideration of [\*\*\*] expenses incurred by Beam prior to the Effective Date.

- **8.2 Technology Transfer Plans; Reimbursement of Costs.** Sana will pay Beam for its costs incurred for performance of any Technology Transfer Plan in accordance with the applicable Technology Transfer Budget. In addition, with respect to any manufacturing transfer, consultation or other assistance the Parties agree that Beam will provide in connection with this Agreement, the Parties will agree in writing in advance upon a budget for reimbursement to Beam of Beam's internal costs (at the then-current FTE Rate) and out-of-pocket costs for such activities. Sana will pay all such costs, consistent with the agreed-upon budget, within [\*\*\*] days after receipt of Beam's invoice. Beam's invoices will include information sufficient to enable Sana to compare the invoiced amounts against the applicable budget.
- **8.3** Additional Option Payments. For each Antigen Target that is designated as an Additional CAR Antigen Target pursuant to Section 3.1(a) and for any Product Type that is designated as an Additional PSC Product Type pursuant to Section 3.1(b), Beam will issue Sana an invoice for a one-time payment equal to ten million Dollars (\$10,000,000) (each, an "Additional Option Payment") and Sana shall pay such Additional Option Payment within [\*\*\*] Business Days after its receipt of such invoice from Beam.
- **8.4 Development Milestone Payments.** Subject to the remainder of this <u>Section 8.4</u>, Sana shall pay to Beam the milestone payments set forth in the "Milestone Payment A" column of the table below (each, a "**Development Milestone Event**") upon the achievement of such Development Milestone Event by a Licensed Product being Developed or Commercialized by or on behalf of Sana or any of its Affiliates or Sublicensees, <u>provided</u>, <u>however</u>, that that in the event that [\*\*\*], Sana shall, in lieu of the amount set forth in the "Milestone Payment A" column in the table below, instead pay to Beam the applicable milestone payment set forth in the "Milestone Payment B" column of the table below.

Development Milestone Event	Milestone Payment A	Milestone Payment B
1.[***]	[***]	[***]
2.[***]	[***]	[***]
3.[***]	[***]	[***]
4.[***]	[***]	[***]
5.[***]	[***]	[***]
6.[***]	[***]	[***]
7.[***]	[***]	[***]
8.[***]	[***]	[***]

(a) Each development milestone payment in this <u>Section 8.4</u> will be non-refundable, non-creditable, and (i) will be payable only once for each Licensed Product, regardless

of the number of times that such milestone event is achieved by such Licensed Product, and (ii) will not be payable (A) with respect to a subsequent achievement of the same Development Milestone Event by a Licensed Product that is a replacement for another Licensed Product, the development of which has been discontinued after achievement of such same Development Milestone Event, (B) with respect to a subsequent achievement of the same Development Milestone Event by any back-up Licensed Product that is a Related Product to a first Licensed Product that has already achieved such same Development Milestone Event, or (C) with respect to a subsequent achievement of the same Development Milestone Event by a Licensed Product that differs from a first Licensed Product that has achieved such same Milestone Event only by virtue of such subsequent Licensed Product's being a different dosage strength or formulation of or using a different delivery system than such first Licensed Product.

- (b) The milestones set forth in this <u>Section 8.4</u> are intended to be successive. If a Licensed Product is not required to undergo the event associated with a particular Development Milestone Event for a given Licensed Product (a "Skipped Milestone"), such Skipped Milestone will be deemed to have been achieved upon the achievement by such Licensed Product of the next successive Development Milestone Event ("Achieved Milestone"). Payment for any Skipped Milestone that is owed in accordance with the provisions of <u>Section 8.4</u> shall be due within [\*\*\*] days after Sana learned of the achievement of the Achieved Milestone. For clarity, [\*\*\*] in a jurisdiction shall not trigger payment of another [\*\*\*] milestone not yet achieved (for example, [\*\*\*] shall not trigger a payment obligation for [\*\*\*], nor vice versa). Additionally, in the event that Sana [\*\*\*] in the table above in this <u>Section 8.4</u> [\*\*\*], the applicable Development Milestone Event 7 or 8 shall be deemed achieved, and the applicable payment will then be due in accordance with this <u>Section 8.4</u>.
- **(c)** Sana will notify Beam within [\*\*\*] days after achievement (or deemed achievement) of each Development Milestone Event. Sana will pay to Beam the corresponding milestone payment set forth in the table above within [\*\*\*] days after achievement of each Development Milestone Event.
- **8.5 Commercial Milestone Payments**. Subject to the remainder of this <u>Section 8.5</u>, Sana shall pay to Beam the milestone payments set forth in the table below when the annual aggregate Net Sales of each Licensed Product first reach the values indicated below (each, a "**Commercial Milestone Event**"); <u>provided, however</u>, that that in the event that [\*\*\*], Sana shall, in lieu of the amount set forth in the "Milestone Payment A" column in the table below, instead pay to Beam the applicable milestone payment set forth in the "Milestone Payment B" column of the table below.

Annual Net Sales of each Licensed Product in the Territory	Milestone Payment A	Milestone Payments B
1.Exceed [***]	[***]	[***]
2.Exceed [***]	[***]	[***]

- (a) Each sales milestone payment in this Section 8.5 will be non-refundable, non-creditable and (i) will be payable only once for each Licensed Product, regardless of the number of times that such Commercial Milestone Event is achieved by such Licensed Product, and (ii) will not be payable (A) with respect to a subsequent achievement of the same Commercial Milestone Event by a Licensed Product that is a replacement for another Licensed Product, the commercialization of which has been discontinued after achievement of such same Milestone Event; (B) with respect to a subsequent achievement of the same Commercial Milestone Event by any back-up Licensed Product that is a Related Product to a first Licensed Product that has already achieved such same Commercial Milestone Event by a Licensed Product that differs from a first Licensed Product that has achieved such same Commercial Milestone Event only by virtue of such subsequent Licensed Product's being a different dosage strength or formulation of or using a different delivery system than such first Licensed Product. For clarity, regardless of the number of Licensed Products that achieve any Commercial Milestone Event, in no event shall Sana pay Beam pursuant to this Section 8.5 more than \$[\*\*\*] with respect to each Licensed Product.
- **(b)** The milestone payments in this <u>Section 8.5</u> shall be additive, such that if more than one Commercial Milestone Event specified above is achieved in the same Calendar Year, then the milestone payments for all such milestone events so achieved shall be payable in the same Calendar Year in accordance with <u>Section 8.5(c)</u>.
- (c) As part of the Calendar Quarterly royalty report in <u>Section 8.7(d)</u>, Sana shall notify Beam if the aggregate annual Net Sales of any Licensed Product first reached a value set forth above during the Calendar Quarter to which such report pertains. Sana shall pay to Beam the applicable sales milestone payments within [\*\*\*] days after the conclusion of the Calendar Quarter in which the applicable Commercial Milestone Event is achieved.
- **8.6** [\*\*\*] **Agreement Milestones**. Notwithstanding anything to the contrary in <u>Section 8.4 or 8.5</u>, if: (a) (i) any event occurs with respect to a Licensed Product or any Enabled Product (as such term is defined in the [\*\*\*] Agreement) developed or commercialized by Sana (or its Affiliates or Sublicensees) triggers a milestone payment by Beam pursuant to the [\*\*\*] Agreement, and (ii) no milestone payment is owed by Sana to Beam under this Agreement or the amount of the milestone payment owed under this Agreement is less than the amount of the milestone payment owed by Beam under the [\*\*\*] Agreement (including as a result of Section 4.5 of the [\*\*\*] Agreement with respect to activities of Sana, its Affiliates and its Sublicensees); then (b) Sana will provide written notice to Beam and pay the amount of such milestone (or gross up its payment to Beam such that the amount of the milestone paid by Sana is not less than that owed by Beam under the [\*\*\*] Agreement) to Beam within [\*\*\*] days after receipt of Beam's invoice therefor.

#### 8.7 Royalty Payments.

**(a) Pass Through Royalty Payments**. Sana shall pay Beam pass-through royalty payments equal to the royalty payments owed by Beam pursuant to the [\*\*\*] Agreement

as a direct result of the Net Sales of each Licensed Product sold by Sana, its Affiliates or Sublicensees that is a Licensed Product or Enabled Product (as defined in the [\*\*\*] Agreement) for the duration of the Royalty Term (as such term is defined in the [\*\*\*] Agreement and as used herein, the "[\*\*\*] **Royalty Term**") in accordance with the terms set forth on **Exhibit F**.

- **(b) Royalty Rates.** Subject to the remainder of this <u>Section 8.7</u>, in addition to the payments set forth in <u>Section 8.7(a)</u>, Sana shall pay Beam [\*\*\*] of all Net Sales of each Licensed Product sold by Sana, its Affiliates or Sublicensees during the Royalty Term.
- Royalty Term. Sana's royalty payment obligations under Section 8.7(b) shall, on a Licensed Product-by- Licensed Product and country-by-country basis, commence on the Effective Date and expire upon the latest of: (i) the expiration of the last to expire Valid Claim within the Beam Patents that Covers such Licensed Product (or if the last Covering Valid Claim with respect to such Licensed Product in such country is a pending Valid Claim, the date such pending Valid Claim ceases to be a Valid Claim; provided, however, that subsequent issuance of such Valid Claim shall again extend the Royalty Term from the date of such issuance to the expiration date of such Valid Claim); (ii) the expiration of all applicable Regulatory Exclusivity, if any, for such Licensed Product in such country; and (iii) ten (10) years after the First Commercial Sale of such Licensed Product in such country (the "Royalty Term"). Upon expiration of a Royalty Term for a Licensed Product in a given country, no further royalty payments will be owed for such Licensed Product in such country pursuant to Section 8.7(b) and the licenses granted to Sana in Section 2.1(b) will automatically become fully paid-up, perpetual and irrevocable with respect to such Licensed Product in such country. Upon expiration of both (A) the Royalty Term for a Licensed Product in a given country and (B) expiration of the [\*\*\*] Royalty Term for such Licensed Product in such country, the license granted to Sana in Section 2.1(b) will automatically become fully paid-up, perpetual, irrevocable, and royalty-free with respect to such Licensed Product in such country.
- (d) Reports and Payment. Within [\*\*\*] days after the end of each Calendar Quarter during the applicable Royalty Term, Sana shall provide Beam with a good faith written estimate of the following information for the applicable Calendar Quarter, on a Licensed Product-by-Licensed Product and country-by-country basis: (A) the amount of gross sales of the each Licensed Product, (B) the number of units of Licensed Products sold, leased or otherwise transferred for the applicable Calendar Quarter; (C) an itemized calculation of Net Sales showing deductions provided for in the definition of "Net Sales," (D) a calculation of the royalty due on such sales, (E) the exchange rate for such country, and (F) whether any sales milestone event has been achieved during such Calendar Quarter (collectively, the "Royalty Information"). Within [\*\*\*] days after the end of each Calendar Quarter during the applicable Royalty Term, Sana shall provide Beam updated, finalized Royalty Information and pay in Dollars all royalty payments due to Beam for such Calendar Quarter.
- **8.8 Payments for Third Party IP Rights**. Except as expressly set forth in <u>Section 8.7(a)</u>, Beam shall remain responsible for all obligations to and payments of royalty, milestone and other payments under Existing Third Party Licenses. To the extent that Beam obtains a license to any Third Party intellectual property rights other than those for which Beam is responsible in this

Section 8.8, and Sana elects to receive a sublicense under such Third Party intellectual property rights pursuant to Section 2.4(b) (thus causing the applicable license agreement to be a Third Party License), Sana shall pay to Beam the applicable portion of any additional payments due arising from Sana's exercise of such Third Party License as provided in Section 2.4(b) in a timely manner, such that Beam may pay such amounts to the applicable Third Party on or before the applicable due date.

- **8.9 Currency; Exchange Rate.** All payments to be made by Sana to Beam under this Agreement shall be computed and paid in Dollars by bank wire transfer in immediately available funds to the bank account set forth on **Exhibit G**, in accordance with the instructions therein. With respect to sales of a Licensed Product and other amounts received that are invoiced in a currency other than U.S. dollars, such amounts and amounts payable will be converted to U.S. dollars using the exchange rate mechanism generally applied by Sana or its Affiliates in preparing its financial statements for the applicable Calendar Quarter, provided that such mechanism is in compliance with GAAP.
- **8.10 Late Payments.** If Beam does not receive payment of any undisputed sum due to it on or before the due date therefor, simple interest shall thereafter accrue on the sum due from the due date until the date of payment at a monthly rate of [\*\*\*] or the maximum rate allowable by applicable Law, whichever is less.

## 8.11 Withholding Taxes.

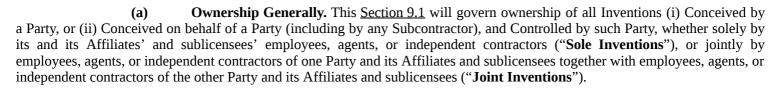
- **(a) Taxes on Income.** Each Party shall be solely responsible for the payment of all taxes imposed on its share of income arising directly or indirectly from the activities of the Parties under this Agreement.
- **(b) Tax Cooperation.** The Parties agree to cooperate with one another and use reasonable efforts to avoid or reduce tax withholding or similar obligations in respect of the milestone payments, royalties and other payments made by Sana to Beam under this Agreement, it being understood and agreed that based on the payment obligations hereunder as of the Effective Date (U.S. party Sana to U.S. party Beam), that no withholding tax is due or applicable to any payment absent Beam's failure to provide a properly executed IRS Form W-9. As such, the sum payable by Sana (in respect of which any deduction or withholding tax may be required to be made, if any) shall, in the case of any withholding tax or similar reduction, be increased to the extent necessary to ensure that Beam receives a sum equal to the sum which it would have received had no such withholding tax applied. To the extent, however, Beam assigns or restructures its rights under the Agreement, including any assignment, sublicense, change of place of incorporation ("**Beam Withholding Tax Action**"), such that a foreign Affiliate or non-U.S. domiciled Beam is entitled to payments hereunder, and as a result thereafter Sana is required to deduct and withhold any additional taxes on any payment to Beam or such Beam Affiliate than previously due, Sana shall pay the amounts of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to Beam an official tax certificate or other evidence of the additional amount of taxes resulting from such Beam Withholding Tax Action with such payment sufficient to enable Beam or such Beam Affiliate to claim such payment of taxes. (By way of example, if the withholding tax rate for which Sana is grossing up its payments to Beam under this

Section 8.11(b) is 15%, and as a result of a Beam Withholding Tax Action the withholding tax rate increases to 20%, then Sana shall continue to gross up Beam for the 15%, but Beam shall cover the economic expense of the additional 5% withholding tax increase caused by the Beam Withholding Tax Action). Such Beam affiliate or Beam shall provide Sana any tax forms that may be reasonably necessary in order for Sana to not withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty, to the extent legally able to do so. Beam shall use reasonable efforts to provide any such tax forms to Sana in advance of the due date. Each Party shall also provide the other Party with reasonable assistance to enable the recovery, as permitted by Law, of withholding taxes or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of Beam.

- **(c) Taxes Resulting from Sana's Action.** If a withholding or deduction obligation arises as a result of any action by Sana, including any assignment, sublicense, change of place of incorporation, or failure to comply with applicable Laws or filing or record retention requirements (an "Sana Withholding Tax Action"), then the sum payable by Sana (in respect of which such deduction or withholding is required to be made) shall be increased to the extent necessary to ensure that Beam receives a sum equal to the sum which it would have received had no such Sana Withholding Tax Action occurred.
- **8.12 Records and Audit Rights.** Sana shall, and shall cause its Affiliates and Sublicensees to, maintain complete and accurate records in sufficient detail to permit Beam to confirm the accuracy of the amount of research and other costs to be reimbursed, achievement of milestones, royalties and other amounts payable under this Agreement for the then current Calendar Year, and during the preceding [\*\*\*] Calendar Years. Upon reasonable prior notice, which shall be no less than upon [\*\*\*] days prior written notice, such records shall be open during regular business hours for a period of [\*\*\*] years from the creation of individual records for examination by an independent certified public accountant selected by Beam and reasonably acceptable to Sana for the sole purpose of verifying for Beam the basis and accuracy of the financial reports furnished by Sana pursuant to this Agreement or of any payments made, or required to be made, by or to the audited party pursuant to this Agreement; provided however, that records for a particular period may only be audited [\*\*\*]. Such audits may occur no more often than [\*\*\*] each Calendar Year. Such auditor shall enter into a confidentiality agreement between the auditor and Beam and not disclose the audited party's Confidential Information to Beam. Any undisputed amounts shown to be owed but unpaid, or overpaid and in need of refund, shall be paid or refunded (as the case may be) within [\*\*\*] days after the accountant's report, plus interest (as set forth in Section 8.10) from the original due date. Beam shall bear the full cost of such audit unless such audit reveals an underpayment by more than [\*\*\*] of the amount due for the entire period being audited, in which case Sana shall reimburse Beam for the reasonable costs for such audit.
- **8.13 Payments**. Notwithstanding the non-refundable or non-creditable nature of any payments hereunder, and except as provided under <u>Section 14.6</u>, nothing in this Agreement shall limit Sana's or its Affiliate's rights to assert or obtain damages for breach of this Agreement, including seeking recoupment from any such payments made.

## ARTICLE 9 INTELLECTUAL PROPERTY RIGHTS

#### 9.1 Inventions.



- **(b) Arising** [\*\*\*] **Inventions**. [\*\*\*] All Arising [\*\*\*] Patents shall be [\*\*\*].
- (c) Arising [\*\*\*] Inventions.
  - (i) [\*\*\*].
  - (ii) [\*\*\*] shall grant and hereby grants to [\*\*\*] under [\*\*\*] rights in and to any Arising

[\*\*\*] Patent:

- (1) a [\*\*\*] license to make, have made, use, sell, offer for sale, import and otherwise exploit [\*\*\*] (the "[\*\*\*]"), which license (in this subclause (1)) shall be [\*\*\*], provided that prior to the [\*\*\*], [\*\*\*] may not grant [\*\*\*] under the [\*\*\*] to [\*\*\*]; and
- (2) a [\*\*\*] license to make, have made, use, sell, offer for sale, import and otherwise exploit any [\*\*\*] (the "[\*\*\*]"), which license (in this subclause (2)) shall be [\*\*\*] (A) to [\*\*\*], and (B) to [\*\*\*], including the [\*\*\*], provided however that [\*\*\*] shall not be permitted to grant [\*\*\*] under this subclause (2)).
- (iii) If upon grant of an Arising [\*\*\*] Patent, there are [\*\*\*], then such [\*\*\*] in accordance with [\*\*\*]. The Parties shall [\*\*\*] the Arising [\*\*\*] Patents [\*\*\*].
- (d) [\*\*\*] Know-How. If [\*\*\*] actually discloses any Know-How within or describing any [\*\*\*] to [\*\*\*] during the Term, (such disclosed Know-How, the "[\*\*\*] Know-How"), then [\*\*\*] shall grant, and hereby grants to [\*\*\*] under such [\*\*\*] Know-How: (i) a [\*\*\*] license in the [\*\*\*], which license (in this subclause (i)) shall be [\*\*\*], and (ii) a [\*\*\*] license in the [\*\*\*], which license (in this subclause (ii)), shall be [\*\*\*], including the [\*\*\*], provided however that [\*\*\*] shall not be permitted to grant [\*\*\*] under this subclause (ii)).
- **(e)** Other Inventions. Except as set forth in [\*\*\*] with respect to [\*\*\*], ownership of all Inventions shall be based [\*\*\*], and (i) each Party shall solely own any Sole Inventions that are not [\*\*\*]; and (ii) the Parties shall jointly own any Joint Inventions that are not [\*\*\*] (including any jointly Conceived [\*\*\*]) ("**Jointly-Owned Inventions**").

- granted to the other Party under this Agreement, including the licenses granted under Section 9.1(c), each Party shall be entitled to practice, license (through multiple tiers), assign (their respective interest only) and otherwise exploit the Jointly-Owned Inventions and Patent Rights claiming patentable Jointly-Owned Inventions ("Jointly-Owned Patents") in all countries and jurisdictions without the duty of accounting or seeking consent from the other Party. For clarity, Jointly-Owned Patents shall include [\*\*\*]. For those countries where a specific license is required for a joint owner of a Jointly-Owned Invention or a Jointly-Owned Patent to practice such Jointly-Owned Invention or Jointly-Owned Patent in such countries, (A) Sana hereby grants to Beam a perpetual, irrevocable, nonexclusive, worldwide, royalty-free, fully paid-up license, with the right to grant sublicenses through multiple tiers, under Sana's right, title and interest in and to all such Jointly-Owned Inventions and Jointly-Owned Patents subject to the terms and conditions of this Agreement, and (B) Beam hereby grants to Sana a perpetual, irrevocable, nonexclusive, worldwide, royalty-free, fully paid-up license, with the right to grant sublicenses through multiple tiers, under Beam's right, title and interest in and to all such Jointly-Owned Inventions and Jointly-Owned Patents to use such Jointly-Owned Patents to use such Jointly-Owned Patents subject to the terms and conditions of this Agreement.
- **(g)** Assignment. [\*\*\*], all rights, title and interests (including all intellectual property rights) in and to any [\*\*\*] and [\*\*\*]. Each Party agrees to, and hereby does, assign and transfer to the other Party, without additional consideration, a joint and undivided interest in and to all Jointly-Owned Inventions and Jointly-Owned Patent, and the other Party hereby accepts such assignment. [\*\*\*] will be deemed [\*\*\*].
- (h) CREATE Act. Notwithstanding anything to the contrary in this Agreement, each Party will have the right to invoke the Cooperative Research and Technology Enhancement Act of 2004, 35 U.S.C. § 103(c)(2)-(c)(3) (the "CREATE Act") when exercising its rights under this Agreement, but to the extent the Patent Rights with respect to which the CREATE Act is invoked or the Patent Rights referenced in respect of such invocation ("Applicable Patent Rights") are comprised, contained or included within Sana Technology, only with the prior written consent of Sana, and with respect to any Applicable Patent Rights comprised, contained or included within Beam Technology, only with the prior written consent of Beam. If a Party intends to invoke the CREATE Act, once agreed to by the other Party if required by the preceding sentence, it will notify the other Party and the other Party will cooperate and coordinate its activities with such Party with respect to any filings or other activities in support thereof. The Parties acknowledge and agree that this Agreement is a "joint research agreement" as defined in the CREATE Act.
- (i) Personnel Obligations. Each employee, agent or independent contractor of a Party or its respective Affiliates or sublicensees performing work under a Technology Transfer Plan shall, prior to commencing such work, be bound by obligations to assign all arising intellectual property, including assignment of all inventions Conceived in the performance of such work, including: (i) promptly reporting any invention, discovery, process or other intellectual property right; (ii) presently assigning to the applicable Party all of his or her right, title and interest in and to any invention, discovery, process or other intellectual property; (iii) cooperating in the

preparation, filing, prosecution, maintenance, defense, and enforcement of any patent and patent application; and (iv) performing all acts and signing, executing, acknowledging and delivering any and all documents required for effecting the obligations and purposes of this Agreement. It is understood and agreed that such invention assignment agreement need not reference or be specific to this Agreement.

#### 9.2 Patent Prosecution.

**(a) Generally.** For the purpose of this <u>Article 9</u>, "prosecution" shall include any post-grant proceeding, including supplemental examination, patent interference proceeding, reissue and reexamination, but excluding any post grant review proceeding, including opposition proceedings, post grant reviews, and inter parties reviews, which shall be governed by <u>Section 9.3</u>.

### (b) Arising [\*\*\*] Patents.

- (i) As between the Parties, [\*\*\*] shall have the sole right, but not the obligation, to file, prosecute and maintain the [\*\*\*] and [\*\*\*] throughout the world, at its sole cost and expense, in [\*\*\*] sole discretion. The Parties shall [\*\*\*], to draft and file any [\*\*\*]. Following disclosure of an [\*\*\*], in connection with any filing of an [\*\*\*], [\*\*\*] shall promptly [\*\*\*].
- **(c) Arising** [\*\*\*] **Patents.** As between the Parties, [\*\*\*] shall have (i) the sole right, but not the obligation, at its discretion and expense, to file a Patent Right Covering any [\*\*\*], and (ii) the right, but not the obligation, at its discretion and expense, to file a Patent Right Covering any [\*\*\*], provided that in each case, [\*\*\*] shall notify [\*\*\*] at least [\*\*\*] prior to the intended filing date of any such patent application, and shall [\*\*\*]. With respect to ongoing prosecution of all [\*\*\*] that are [\*\*\*] Patents, [\*\*\*] shall apply. In all cases, [\*\*\*] shall notify [\*\*\*] following any filing of an [\*\*\*].

### (d) Jointly-Owned Patents.

- (i) Generally. Except as set forth in [\*\*\*] with respect to [\*\*\*], prior to the filing of any Jointly-Owned Patent anywhere in the world, upon the request of either Party, the Parties shall meet and discuss in good faith the allocation of rights and responsibilities between the Parties with respect to such activities for such Jointly-Owned Patents. If the Parties cannot agree on such allocation within a period of [\*\*\*] days after the applicable Party's receipt of such request, then such dispute shall be referred to the Executive Officers of the Parties for resolution. Absent any such agreement between the Parties, neither Party shall file a Jointly-Owned Patent in any county or jurisdiction in the world unless failing to do so would have a material adverse impact on the patentability of such Jointly-Owned Invention in such country or jurisdiction.
- **(ii) Cooperation**. With respect to Jointly-Owned Patents, the Party responsible for prosecution activities (the "**Prosecuting Party**") shall keep the other Party fully informed of all steps with regard to the preparation, filing, prosecution and maintenance of Jointly-Owned Patents, including by providing such other Party with a copy of material communications to and from any patent authority regarding such Jointly-Owned Patents, and by providing such other Party drafts of any material filings or responses to be made to such patent authorities sufficiently in advance of submitting such filings or responses so as to allow for a reasonable

opportunity for such other Party to review and comment thereon. The Prosecuting Party shall consider in good faith the requests and suggestions of the other Party with respect to the Prosecuting Party's drafts and with respect to strategies for filing and prosecuting the Jointly-Owned Patents in the Territory. If the Prosecuting Party decides not to prepare, file, prosecute, maintain, continue the prosecution and maintenance of, or continue to pay the expenses for the prosecution and maintenance of, a Jointly-Owned Patent in a country or other jurisdiction in the Territory, the Prosecuting Party shall timely provide reasonable prior written notice to the other Party of such intention, and such other Party (the "Assuming Party") shall thereupon have the option, in its sole discretion, to assume the control and direction of the preparation, filing, prosecution and maintenance of such Jointly-Owned Patent at its expense in such country or other jurisdiction. In such case the Assuming Party shall assume the responsibility and control for the preparation, filing, prosecution and maintenance of such Jointly-Owned Patent. In such event, the Prosecuting Party shall reasonably cooperate with the Assuming Party (as the new Prosecuting Party, *mutatis mutandis*) in such country or other jurisdiction as provided under this Section 9.2(d)(ii).

#### 9.3 Patent Enforcement and Defense.

- (a) [\*\*\*] **Patents.** [\*\*\*] shall have the [\*\*\*] right, but not the obligation, to bring and control, at its own cost and expense, any legal action in connection with any infringement or defense of any [\*\*\*] Patents and [\*\*\*], and [\*\*\*] from such action.
- **(b) Cooperation.** The Parties agree to cooperate fully in any infringement or defense action in connection with any Patent Controlled by such Party that Covers Inventions set forth in [\*\*\*] (a "**Relevant Enforcement Action**"). If and to the extent necessary for a Party (the "**Enforcing Party**") to bring such a Relevant Enforcement Action, the other Party shall, where necessary, furnish a power of attorney solely for such purpose or shall join in, or be named as a necessary party to, such action. Unless otherwise set forth herein, the Enforcing Party shall have the right to settle such claim; provided that neither Party shall have the right to settle any Relevant Enforcement Action in a manner that materially diminishes or has a material adverse effect on the rights or interest of the other Party, or in a manner that imposes any costs or liability on, or involves any admission by, the other Party, without the express written consent of such other Party. To the extent that a Party is joined to any Relevant Enforcement Action, the Enforcing Party shall provide the joined Party with copies of all pleadings and other documents filed with the court and shall consider reasonable input from the joined Party during the course of the proceedings.
- **(c) Recovery.** Any recovery realized as a result of a Relevant Enforcement Action (whether by way of settlement or otherwise) shall be first allocated to reimburse the Parties for their costs and expenses in making such recovery (which amounts shall be allocated pro rata if insufficient to cover the totality of such expenses). Any remainder after such reimbursement is made shall be retained by the Enforcing Party; provided that to the extent that any award or settlement (whether by judgment or otherwise) is attributable to loss of sales with respect to a Licensed Product and retained by Sana, such amounts shall [\*\*\*].
- **9.4 Patent Extensions.** Subject to any separate agreement between the Parties governing activities with respect to Jointly-Owned Patents, the Parties shall cooperate in obtaining

patent term restoration (under but not limited to the U.S. Drug Price Competition and Patent Term Restoration Act), supplemental protection certificates or their equivalents, and patent term extensions with respect to the Jointly-Owned Patents in any country and/or region where applicable; provided that if the Parties fail to agree, Sana shall have the final decision-making authority over whether to extend (or apply for any equivalent with respect to) any Jointly-Owned Patent. Sana shall file for such extensions at Sana's sole cost and expense.

- **9.5 Patents Licensed from Third Parties**. Each Party's rights under this <u>Article 9</u> with respect to the prosecution and enforcement of any [\*\*\*] that is licensed [\*\*\*] from a Third Party shall be subject to the rights retained by such Third Party to prosecute and enforce such Patent Rights.
- **9.6 Trademarks.** Sana shall have the right to brand Licensed Products using Sana related trademarks and any other trademarks and trade names it determines appropriate, which may vary by country or within a country ("**Product Marks**"). Sana shall own all rights in the Product Marks and shall have the right to register and maintain the Product Marks in the countries and regions that it determines reasonably necessary, at Sana's cost and expense.

## ARTICLE 10 CONFIDENTIALITY; PUBLICATION

- **10.1 Duty of Confidence.** Subject to the other provisions of this <u>Article 10</u>:
- (a) all Confidential Information of a Party (the "**Disclosing Party**") shall be maintained in confidence and otherwise safeguarded by the other Party (the "**Receiving Party**") and its Affiliates, in the same manner and with the same protections as the Receiving Party maintains its own confidential information, but in any event no less than reasonable efforts;
- **(b)** the Receiving Party may only use any such Confidential Information for the purposes of performing its obligations or exercising its rights under this Agreement; and
- (c) the Receiving Party may only disclose Confidential Information of the other Party to: (i) its Affiliates, licensees, sublicensees and permitted assignees; and (ii) employees, directors, agents, contractors, consultants and advisers of the Receiving Party and its Affiliates, licensees, sublicensees and permitted assignees, in each case to the extent reasonably necessary for the purposes of, and for those matters undertaken pursuant to, this Agreement; provided that such Persons are bound by legally enforceable obligations to maintain the confidentiality of the Confidential Information in a manner consistent with the confidentiality provisions of this Agreement.
- **10.2 Exceptions.** The foregoing obligations as to particular Confidential Information of a Disclosing Party shall not apply to the extent that the Receiving Party can demonstrate that such Confidential Information:

- (a) is known by the Receiving Party at the time of its receipt without an obligation of confidentiality, and not through a prior disclosure by the Disclosing Party, as documented by the Receiving Party's business records;
- **(b)** is available to the public before its receipt from the Disclosing Party, or thereafter becomes available to the public through no fault of the Receiving Party;
- (c) is subsequently disclosed to the Receiving Party by a Third Party who may lawfully do so and is not under an obligation of confidentiality to the Disclosing Party; or
- **(d)** is developed by the Receiving Party independently and without use of or reference to any Confidential Information received from the Disclosing Party, as documented by the Receiving Party's business records.

Any combination of features or disclosures shall not be deemed to fall within the foregoing exclusions merely because individual features are published or available to the general public or in the rightful possession of the Receiving Party unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the Receiving Party.

- **10.3 Authorized Disclosures.** Notwithstanding the obligations set forth in <u>Sections 10.1</u> and <u>10.5</u>, a Party may disclose the other Party's Confidential Information (including this Agreement and the terms herein) to the extent:
- (a) such disclosure is reasonably necessary: (i) to such Party's or its Affiliates' directors, attorneys, independent accountants, financial advisors or other representatives for the sole purpose of enabling such directors, attorneys, independent accountants financial advisors or other representatives to provide advice to such Party or Affiliate, provided that in each such case such recipients are bound by confidentiality and non-use obligations substantially consistent with those contained in this Agreement; or (ii) to actual or potential investors, acquirors, licensees and other financial or commercial partners solely for the purpose of evaluating or carrying out an actual or potential investment, acquisition or collaboration, provided that in each such case such recipients are bound by confidentiality and non-use obligations substantially consistent with those contained in the Agreement;
- (b) such disclosure is required by Law, or judicial or administrative process, provided that in such event such Party shall promptly inform the other Party of such required disclosure and provide the other Party an opportunity to challenge or limit the disclosure obligations. Confidential Information that is disclosed pursuant to this <u>Section 10.3(b)</u> shall remain otherwise subject to the confidentiality and non-use provisions of this <u>Article 10</u>, and the Party disclosing Confidential Information pursuant to Law or court order shall cooperate with and reasonably assist the other Party (at the other Party's expense) if the other Party seeks a protective order or other remedy in respect of any such disclosure and furnish only that portion of the Confidential Information which, in the opinion of such Party's legal counsel, is responsive to such requirement; or

- **(c)** such disclosure is by Beam and is required pursuant to the terms of any Third Party License, provided that in each such case such Third Parties are bound by confidentiality and non-use obligations substantially consistent with those contained in the Agreement.
- **10.4 Scientific Publication.** Each Party shall have the right to make publications in accordance with this <u>Section 10.4</u>; provided that any publication by Beam that relates to Licensed Products and is not primarily directed to Beam Platform Technology shall be subject to Sana's prior written consent (which may be withheld or denied in its sole discretion). Consequently, either Party or its Affiliates shall deliver to the other Party for review and comment a copy of any scientific proposed publication or presentation of technology that describes or contains the other Party's Confidential Information, at least [\*\*\*] days prior to the date of disclosure. During such [\*\*\*] day period, the reviewing Party shall have the right to require modifications of the publication or presentation: (a) to protect the Parties' Confidential Information; (b) for trade secret reasons or reasonable business reasons; and/or (c) to delay such submission for an additional period up to [\*\*\*] days as may be reasonably necessary to seek patent protection for the information disclosed in such proposed submission. The Parties shall comply with traditional standards of authorship with respect to scientific publications.

### 10.5 Publicity; Use of Names.

- (a) The Parties may mutually agree on language of a joint press release announcing this Agreement which may be issued by the Parties at a mutually agreed time after the Effective Date. Subject to Section 10.3, no public disclosure of the existence or the terms of this Agreement may be made by either Party or its Affiliates except as provided in this Section 10.5, and no Party shall use the name, trademark, trade name or logo of the other Party, its Affiliates or their respective employees in any publicity, promotion, news release or disclosure relating to this Agreement or its subject matter, except as provided in this Section 10.5, as may be required by applicable Law, or with the prior express written permission of the other Party. Notwithstanding the foregoing, Beam may use Sana's name and logo in connection on its website, in marketing materials and presentations and in other communications to identify Sana as a licensee of the Beam Technology.
- **(b)** A Party may disclose this Agreement and its terms, in securities filings with the Securities Exchange Commission (the "SEC") or equivalent foreign agency to the extent required by applicable Law after complying with the procedure set forth in this Section 10.5(b). In such event, the Party seeking such disclosure shall prepare a proposed redacted version of this Agreement and the other Party agrees to promptly (and in any event, within [\*\*\*] Business Days after receipt of such proposed redactions) give its input in a reasonable manner in order to allow the Party seeking disclosure to file the version of this Agreement within the timelines proscribed by applicable Law. The Party seeking such disclosure shall reasonably consider any comments thereto provided by the other Party within such [\*\*\*] Business Day period, and shall use reasonable efforts to obtain confidential treatment of this Agreement from the SEC (or equivalent foreign agency) as represented by the redacted version revised by the other Party. If both Parties are seeking such disclosure, then the Parties shall mutually agree upon a proposed redacted version

of this Agreement and each Party shall use reasonable efforts to obtain confidential treatment of such agreed upon redacted version of this Agreement from the SEC (or equivalent foreign agency).

- (c) Each Party acknowledges that the other Party may be legally required to make public disclosures (including in filings with the Governmental Authorities) of certain terms of or material developments or material information generated under this Agreement and agrees that each Party may make such disclosures as required by Law, provided that the Party seeking such disclosure first provides the other Party a copy of the proposed disclosure, and shall reasonably consider any comments thereto provided by the other Party within [\*\*\*] Business Days after the receipt of such proposed disclosure or such shorter period required to comply with applicable Law.
- (d) The Parties agree that the portions of any other news release or other public announcement relating to this Agreement or the performance hereunder that would disclose information that is not already available to the public, shall first be reviewed and approved by both Parties within [\*\*\*] Business Days after the receipt of such proposed disclosure. Notwithstanding the foregoing, Sana and its Affiliates shall have the right to disclose publicly any information relating to the development, manufacture or commercialization of any Licensed Products hereunder that does not include Confidential Information of Beam.
- (e) The Parties agree that after a disclosure pursuant to  $\underline{Section\ 10.5(a)}$ ,  $\underline{10.5(b)}$ ,  $\underline{10.5(c)}$  or  $\underline{10.5(d)}$  has been reviewed and approved by the other Party, the disclosing Party may make subsequent public disclosures for a purpose permitted under this  $\underline{Section\ 10.5}$  reiterating such information without having to obtain the other Party's prior consent and approval.

#### ARTICLE 11 TERM AND TERMINATION

**11.1 Term.** The term of this Agreement shall commence upon the Effective Date and continue in full force and effect, on a Licensed Product-by-Licensed Product and country-by-country basis, until such time as both the Royalty Term and the [\*\*\*] Royalty Term with respect to such Licensed Product expires in such country (the "**Term**"). Upon expiration of the Term in its entirety, the license granted to Sana in <u>Section 2.1(b)</u> will, to the extent not already provided for under <u>Section 8.7(c)</u>, automatically become fully paid-up, perpetual and irrevocable with respect to all Licensed Products in the Territory.

#### 11.2 Termination.

(a) Termination by Sana for Convenience. Sana may terminate this Agreement in its entirety or on a CAR Antigen Target-by-CAR Antigen Target basis (with respect to all Licensed Products for the applicable CAR Antigen Target), PSC Product Type-by-PSC Product Type basis (with respect to all Licensed Products for the applicable PSC Product Type) or Licensed Product-by-Licensed Product basis by providing written notice of termination to Beam, which notice specifies the scope of the termination and includes an effective date of termination at least (i) ninety (90) days after the date of the notice if such notice is provided prior to First Commercial Sale of any Licensed Product or (ii) one hundred eighty (180) days after the date of

the notice if such notice is provided after First Commercial Sale of any Licensed Product. If Sana terminates this Agreement pursuant to this <u>Section 11.2(a)</u> with respect to particular CAR Antigen Targets or Licensed Products and subsequently terminates this Agreement pursuant to this <u>Section 11.2(a)</u> with respect to all remaining CAR Antigen Targets or Licensed Products, then the Agreement shall terminate in its entirety upon the effective date of such subsequent termination.

- **(b) Termination for Material Breach.** Each Party shall have the right to terminate this Agreement solely with respect to the country to which such uncured material breach relates upon written notice to the other Party, if such other Party commits a material breach of this Agreement and, after receiving written notice from the non-breaching Party identifying such material breach in reasonable detail, fails to cure such material breach within [\*\*\*] days ([\*\*\*] days in the event of a payment breach) from the date of such notice; *provided*, *that* if such breach is not reasonably capable of cure within such [\*\*\*]-day ([\*\*\*] days in the event of a payment breach) period, the breaching Party may submit a reasonable cure plan prior to the end of such [\*\*\*]-day ([\*\*\*] days in the event of a payment breach) period, in which case the other Party may, at its sole discretion, determine not to terminate this Agreement for so long as the breaching Party is using diligent efforts to implement such cure plan.
- (c) **Termination for Bankruptcy.** This Agreement may be terminated at any time during the Term by either Party upon the other Party's filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party; provided that in the case of any involuntary bankruptcy proceeding such right to terminate shall only become effective if the Party consents to the involuntary bankruptcy or such proceeding is not dismissed within [\*\*\*] days after the filing thereof. All rights and licenses granted under or pursuant to this Agreement by a Party are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that each Party, as licensee of intellectual property under this Agreement, shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code. The Parties further agree that in the event of a rejection of this Agreement by a Party in any bankruptcy proceeding by or against such Party under the U.S. Bankruptcy Code, (i) the other Party shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property that are necessary for the other Party to practice its license to such intellectual property, which, if not already in such other Party's possession, shall be promptly delivered to it upon its written request therefor, and (ii) such Party shall not interfere with the other Party's rights to such intellectual property, and shall assist and not interfere with such other Party in obtaining such intellectual property and such embodiments of such intellectual property from another entity. The term "embodiments" of intellectual property means all tangible embodiments of the intellectual property licensed hereunder to the extent of the license scope, and shall exclude all inventory of Licensed Products and filings with Regulatory Authorities. All rights, powers and remedies provided in this Section 11.2(c) are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at Law or in equity (including the Bankruptcy Code) in the event of the commencement of a case under the U.S. Bankruptcy Code.

(d) Termination for Patent Challenge. If Sana or any of its Affiliates or Sublicensees directly or indirectly brings, assumes or participates in, or knowingly, willfully or recklessly assists in bringing a Patent Challenge (except as required under a court order or subpoena), then the following shall apply: (a) if Sana or any of its Affiliates is the party so bringing, assuming, participating in or assisting in such Patent Challenge, then Beam shall be entitled to immediately terminate this Agreement upon written notice to Sana, and (b) if a Sublicensee of Sana is the party so bringing, assuming, participating in or assisting in such Patent Challenge, then (i) Beam shall be entitled to immediately terminate the rights hereunder as and to the extent sublicensed to a Sublicensee upon written notice to Sana, and (ii) Beam shall grant Sana a period not to exceed [\*\*\*] days from the date of notice by Beam to Sana for Sana to inform the applicable Sublicensee of its intention to terminate this Agreement due to such Sublicensee bringing, assuming, participating in or assisting in a Patent Challenge, during which period Sana may terminate any and all agreements with such Sublicensee that contain a Sublicense under the Beam Patents. If, pursuant to the foregoing subclause (ii), Sana terminates such Sublicensee agreement(s) during such [\*\*\*] day period, then Beam shall not be entitled to terminate this Agreement, in whole or in part, by virtue of such Sublicensee bringing, assuming, participating in or assisting in such Patent Challenge. However, if Sana does not terminate such agreement(s) during such [\*\*\*] day period, then Beam shall be entitled to immediately terminate this Agreement in whole or in part upon written notice to Sana thereof.

#### 11.3 Effect of Termination.

- (a) Upon the termination of this Agreement for any reason, all rights and obligations of each Party hereunder will cease, except as otherwise expressly provided herein; provided that if such termination is with respect to one or more specified CAR Antigen Targets, PSC Product Types or Licensed Products, then such rights and obligations shall cease solely with respect to such terminated CAR Antigen Targets (and their applicable Licensed Product(s)), PSC Product Types (and their applicable Licensed Product(s)) or such Licensed Products, as applicable, and, in the case of termination with respect to (i) one or more specified CAR Antigen Targets, with respect to activities occurring during the remainder of the Term of this Agreement, each such terminated CAR Antigen Target shall no longer be considered a CAR Antigen Target or (ii) one or more specified PSC Product Types, with respect to activities occurring during the remainder of the Term of this Agreement, each such terminated PSC Product Types shall no longer be considered a PSC Product Type.
- **(b)** Upon termination of this Agreement for any reason, each Party shall promptly return to the other Party or destroy, at the owning Party's request, all Confidential Information of such other Party.
- **11.4 Termination of the** [\*\*\*] **Agreement**. Sana acknowledges and agrees that pursuant to <u>Section 2.4.2.6</u> of the [\*\*\*] Agreement, if the [\*\*\*] Agreement is terminated by the [\*\*\*], or if the licenses granted to Beam by the [\*\*\*] under any [\*\*\*] Patent Rights are terminated by the [\*\*\*] in whole or in part (e.g., as to termination in a particular country), this Agreement shall automatically terminate to the extent of the terminated license.

- **11.5 Survival.** Upon expiration or termination of this Agreement, all rights, license and obligations of the Parties under this Agreement shall cease, except that the following will survive and continue in effect thereafter: (a) payment obligations under Article 8; (b) remedies for breach of this Agreement; and (c) the provisions of <u>Article 1</u> (to the extent necessary to interpret other surviving sections), <u>Article 8</u>, <u>Section 9.1</u>, <u>Section 9.2</u>, <u>Article 10</u>, <u>Section 11.3</u>, <u>Section 11.5</u>, <u>Section 12.5</u>, <u>Article 13</u>, <u>Article 14</u> of this Agreement; and (d) the provisions of Articles 5, 9, 10 and 11, and Sections 4.5, 4.7, 8.5 and 8.6 of the [\*\*\*] Agreement as they relate to this Agreement.
- **11.6 Termination Not Sole Remedy.** Termination is not the sole remedy under this Agreement and, whether or not termination is effected and notwithstanding anything contained in this Agreement to the contrary, all other remedies shall remain available except as agreed to otherwise herein.

### ARTICLE 12 REPRESENTATIONS AND WARRANTIES

- **12.1 Mutual Representations and Warranties.** Each Party represents, warrants to the other Party as of the Effective Date that:
- **(a) Organization**. Such Party is duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is organized.
- **(b)** Authorization and Enforcement of Obligations. Such Party: (i) has the requisite power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder, and (ii) has taken all requisite action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation, enforceable against such Party in accordance with its terms.
- **(c) Consents.** All necessary consents, approvals and authorizations of all Governmental Authorities and other Persons required to be obtained by such Party in connection with the execution and delivery of this Agreement have been obtained.
- **(d) No Conflict**. The execution and delivery of this Agreement and the performance of such Party's obligations hereunder: (i) do not conflict with or violate any requirement of applicable Laws of Governmental Authorities, (ii) do not conflict with, or constitute a breach or default under, any contractual obligation of such Party, and (iii) do not conflict with or result in a breach of any provision of the organizational documents of such Party.
- **12.2 Representations and Warranties by Beam.** Beam represents and warrants to Sana as of the Effective Date that:
- (a) it has the right to grant the licenses granted to Sana under <u>Section 2.1</u> and perform its obligations under this Agreement;

- **(b)** it has not received any written notice from any Third Party asserting or alleging that the practice or use of Beam Technology infringed or misappropriated the intellectual property rights of such Third Party;
- (c) there are no judgments, orders, decrees, or settlements against or owed by Beam or any of its Affiliates, and, and there is no claim, demand, suit, proceeding, arbitration, inquiry, investigation or other legal action of any nature, civil, criminal, regulatory or otherwise, pending or, to the Knowledge of Beam, threatened against Beam or any of its Affiliates, in each case relating to the Beam Technology or the transactions contemplated by this Agreement;
  - **(d)** Beam Controls the Beam Patents listed on **Exhibit A**;
- **(e)** [\*\*\*], (i) **Exhibit A** set forth a true and complete list of all Beam Patents (A) owned or otherwise Controlled by Beam or its Affiliates as of the Effective Date or (B) to which Beam or its Affiliates have as of the Effective Date been granted or otherwise transferred any right to practice under, in each case that constitute Beam Technology, (ii) except for expired provisional patent applications, each such Patent Right, is in full force and effect, and (iii) Beam or its Affiliates have timely paid, or caused the appropriate Third Parties to pay, all filing and renewal fees payable with respect to such Patent Rights;
- **(f)** [\*\*\*], no Third Party (i) has challenged or threatened to challenge the inventorship, ownership, Beam's right to use, scope, validity or enforceability of, or Beam's rights in or to, any Beam Patents (including, by way of example, through the institution or written threat of institution of interference, derivation, post-grant review, opposition, nullity or similar invalidity proceedings before the United States Patent and Trademark Office or any analogous foreign Governmental Authority);
- **(g)** Beam (i) (or, with respect to Beam Patents licensed under Existing Third Party Licenses, [\*\*\*], the applicable Existing Third Party Licensor), has obtained from all inventors of the Beam Patents, valid and enforceable agreements assigning to Beam or such licensor each such inventor's entire right, title and interest in and to all such Beam Patents; and (ii) has no Knowledge of any Person (other than Persons identified in the applicable patent applications or patents, as inventors of inventions claimed in the Beam Patents) who claims to be an inventor of an invention claimed in the Beam Patents; and
- (h) (i) there are no Existing Third Party Licenses other than those set forth on Exhibit B, (ii) a copy of each Existing Third Party License have been provided to Sana and each such copy is true and complete with respect to all unredacted portions provided to Sana (and no redacted portion of any such Existing Third Party License (A) renders any portion of such copy provided to Sana materially untrue or misleading or (B) materially limits or alters the rights granted to Sana pursuant to this Agreement), (iii) no Third Party has any right, title or interest in or to, or any license under, any Beam Technology that conflicts with the rights granted to Sana hereunder, (iv) no rights granted by or to Beam or its Affiliates under any Existing Third Party License conflict with any right or license granted to Sana hereunder and (v) Beam and its Affiliates are in compliance in all material respects with all Existing Third Party Licenses.

#### 12.3 Beam Covenants

. In addition to the covenants made by Beam elsewhere in this Agreement, Beam hereby covenants to Sana that, from the Effective Date until expiration or termination of this Agreement:

- (a) Beam will not, and will cause its Affiliates not to (i) license, sell, or assign (other than in a connection with a permitted assignment of this Agreement by Beam pursuant to Section 14.3) or otherwise transfer to any Person (other than Sana or its Affiliates or Sublicensees pursuant to the terms of this Agreement) any Beam Technology (or agree to do any of the foregoing) in a manner that would materially conflict with the licenses and other rights granted to Sana under this Agreement or frustrate the purpose of this Agreement; or (ii) incur or permit to exist, with respect to any Beam Technology, any lien, encumbrance, charge, security interest, mortgage, liability, assignment, grant of license or other binding obligation in each case that would materially conflict with the licenses and other rights granted to Sana under this Agreement or frustrate the purpose of this Agreement; provided however, that the foregoing will not prevent the grant of a lien or security interest to secure obligations to the lender in a financing transaction to the extent that such grant does not conflict with any of the rights or licenses granted to Sana hereunder;
- **(b)** Beam will not (i) take any action with respect to any Third Party License (including amending, terminating or otherwise modifying) that materially diminishes the rights under the Beam Technology granted to Sana under this Agreement or that materially increases Sana's obligations under this Agreement with respect to Sana's exploitation of its sublicense with respect to such Third Party License under this Agreement; or (ii) fail to take any action with respect to a Third Party License that is reasonably necessary to avoid materially diminishing the rights under the Beam Technology granted to Sana under this Agreement; and
- **(c)** Beam will (i) not enter into, amend or modify any Third Party License that materially adversely affects (A) the rights granted to Sana, Sana's Affiliates or Sublicensees hereunder or (B) Beam's ability to fully perform its obligations hereunder; and (ii) promptly furnish Sana with true and complete copies of all (A) amendments to the Existing Third Party Licenses and (B) to the extent required under Section 2.4(b), Third Party Licenses executed following the Effective Date.

#### 12.4 Mutual Covenants.

- **(a) No Debarment.** In the course of the research, development, manufacture and commercialization of the Licensed Products, neither Party nor its Affiliates or sublicensees shall use any employee or consultant who has been debarred by any Regulatory Authority, or is the subject of debarment proceedings by a Regulatory Authority. Each Party shall notify the other Party promptly upon becoming aware that any of its or its Affiliates' or sublicensees' employees or consultants has been debarred or is the subject of debarment proceedings by any Regulatory Authority.
- **(b) Compliance**. Each Party and its Affiliates shall comply in all material respects with all applicable Laws (including all anti-bribery laws) in the research, development,

manufacture and commercialization of the Licensed Products and performance of its obligations under this Agreement.

12.5 No Other Warranties. EXCEPT AS EXPRESSLY STATED IN THIS ARTICLE 12, (A) NO REPRESENTATION, CONDITION OR WARRANTY WHATSOEVER IS MADE OR GIVEN BY OR ON BEHALF OF SANA OR BEAM; AND (B) ALL OTHER CONDITIONS AND WARRANTIES WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE ARE HEREBY EXPRESSLY EXCLUDED, INCLUDING ANY CONDITIONS AND WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT. WITHOUT EXCUSING EITHER PARTY'S PERFORMANCE OF ITS OBLIGATIONS UNDER THIS AGREEMENT, EACH PARTY HEREBY DISCLAIMS ANY REPRESENTATION OR WARRANTY THAT THE RESEARCH, DEVELOPMENT, MANUFACTURE OR COMMERCIALIZATION OF ANY CELL CONSTRUCT OR PRODUCT PURSUANT TO THIS AGREEMENT WILL BE SUCCESSFUL.

### ARTICLE 13 INDEMNIFICATION; LIABILITY; INSURANCE

- **13.1 Indemnification by Beam.** Beam shall indemnify, defend and hold harmless Sana and its Affiliates and Sublicensees, and each of their respective directors, officers, employees and agents (collectively "Sana Indemnitees"), from and against all losses, liabilities, damages and expenses, including reasonable attorneys' fees and costs (collectively, "Liabilities"), to the extent resulting from any claims, demands, actions or other proceedings by any Third Party arising out of:
  - (a) the breach of any representation, warranty or covenant by Beam under this Agreement; or
  - (b) the recklessness, negligence or intentional misconduct of any Beam Indemnitees; or
- (c) any activities by or on behalf of Beam or its Affiliates or contractors under or in connection with its performance under a Technology Transfer Plan;

except, in each case, to the extent arising out of any activities set forth in <u>Section 13.2</u> for which Sana is obligated to indemnify the Beam Indemnitees.

- **13.2 Indemnification by Sana.** Sana shall indemnify, defend and hold harmless Beam and its Affiliates, and each of their respective directors, officers, employees and agents (collectively "**Beam Indemnitees**"), from and against all Liabilities to the extent resulting from any claims, demands, actions or other proceedings by any Third Party arising out of:
  - (a) the breach of any representation, warranty or covenant by Sana under this Agreement;

- **(b)** the recklessness, negligence or intentional misconduct of any Sana Indemnitees;
- (c) any activities by or on behalf of Sana or its Affiliates or contractors under or in connection with its performance under a Technology Transfer Plan; or
- **(d)** the development, manufacture, sale, or other commercialization of any Licensed Products in the Field by or on behalf of Sana or its Affiliates or Sublicensees;

except, in each case, to the extent arising out of any activities set forth in <u>Section 13.1</u> for which Beam is obligated to indemnify the Sana Indemnitees.

**Indemnification of the Upstream Licensors.** Sana shall indemnify, defend and hold harmless each of the 13.3 [\*\*\*] and each Other Institution and each of their current and former directors, governing board members, trustees, officers, faculty, affiliated investigators, medical and professional staff, employees, students, and agents and their respective successors, heirs and assigns (collectively, the "[\*\*\*] Indemnitees") from and against any claim, suit, investigation, action, demand, judgment, liability, cost, expense, damage, deficiency, loss or obligation of any kind or nature (including reasonable attorneys' fees and other costs and expenses of litigation or defense), based upon, arising out of, or otherwise relating to this Agreement, including any cause of action relating to product liability concerning any product, process, or service made, used, sold or performed pursuant to any right or license granted under this Agreement (collectively, "Claims") except to the extent any such Claim results from or arises out of the gross negligence or willful misconduct of any [\*\*\*] Indemnitee or material breach of the [\*\*\*] Agreement by the [\*\*\*]. No Affiliate of Sana (other than an Affiliate controlling Sana) shall have an obligation to indemnify any [\*\*\*] Indemnitee for any Claim based upon, arising out of, or otherwise relating to the exercise of rights under this Agreement by a different Affiliate of Sana or by any other Person unless such Affiliate or other Person is exercising rights granted by such first Affiliate or acting on such first Affiliate's behalf or upon its instruction or advice. Sana shall have no obligation to indemnify any [\*\*\*] Indemnitee for any Claim based upon, arising out of, or otherwise relating to the exercise of rights under the [\*\*\*] Agreement by a different sublicensee of Beam, or by Beam, any Affiliate of Beam or by any other Person unless such different sublicensee, Beam or Affiliate or other Person is exercising rights granted by Sana or acting on Sana's behalf or upon its instruction or advice.

#### 13.4 Indemnification Procedure.

(a) Notification. If either Party is seeking indemnification under <u>Section 13.1</u> or Section <u>13.2</u> (the "**Indemnified Party**"), it shall inform the other Party (the "**Indemnifying Party**") of the claim giving rise to the obligation to indemnify pursuant to such Section as soon as reasonably practicable after receiving notice of the claim provided, however, that no delay on the part of the Indemnified Party in notifying the Indemnifying Party will relieve the Indemnifying Party from any obligation hereunder unless (and then only to the extent that) the Indemnifying Party is prejudiced thereby.

- Control. The Indemnifying Party shall have the right, exercisable by notice to the Indemnified Party within [\*\*\*] days after receipt of notice from the Indemnified Party of the commencement of or assertion of any Third Party Claim, to assume the direction and control of the defense, litigation, settlement, appeal or other disposition of any such claim for which it is obligated to indemnify the Indemnified Party (including the right to settle the claim solely for monetary consideration) with counsel selected by the Indemnifying Party and reasonably acceptable to the Indemnified Party. During such time as the Indemnifying Party is controlling the defense of such Third Party Claim, the Indemnified Party shall reasonably cooperate with the Indemnifying Party in such defense at the Indemnifying Party's request and expense. If the Indemnifying Party does not notify the Indemnified Party of the Indemnifying Party's intent to defend any Third Party Claim within [\*\*\*] days after notice thereof, the Indemnified Party may (with notice to the Indemnifying Party) undertake the defense thereof with counsel of its choice and at the Indemnifying Party's expense (including reasonable, out-of-pocket attorneys' fees and costs and expenses of enforcement or defense). The Indemnifying Party or the Indemnified Party, as the case may be, shall have the right to participate (including the right to conduct discovery, interview and examine witnesses and participate in all settlement conferences), but not control, at its own expense and with counsel of its choice, in the defense of any claim that has been assumed by the other Party.
- **(c) Settlement**. Neither Party shall have the obligation to indemnify the other Party in connection with any settlement made without the Indemnifying Party's written consent, which consent shall not be unreasonably withheld or delayed.
- **(d) Upstream Indemnification**. Any claim for indemnification that arises in connection with <u>Section 13.3</u> shall be governed by Section 9.1.2 of the [\*\*\*] Agreement.
- **13.5 Mitigation of Loss.** Each Indemnified Party shall take and shall procure that its Affiliates take all such reasonable steps and action as are reasonably necessary or as the Indemnifying Party may reasonably require in order to mitigate any claims (or potential losses or damages) under this Article 13. Nothing in this Agreement shall or shall be deemed to relieve any Party of any common law or other duty to mitigate any losses incurred by it.

#### 13.6 Insurance.

(a) Beginning at the time any Licensed Product is being commercially distributed or sold (other than for the purpose of obtaining Marketing Approvals) by Sana, or by an Affiliate, Sublicensee or agent of Sana, Sana shall, at its sole cost and expense, procure and maintain commercial general liability insurance in amounts not less than \$[\*\*\*] per incident and \$[\*\*\*] annual aggregate and naming the Indemnitees as additional insureds. During Clinical Studies (as defined in the [\*\*\*] Agreement) of any such Licensed Product Sana shall, at its sole cost and expense, procure and maintain commercial general liability insurance in such equal or lesser amount as Beam, [\*\*\*] or any other Institution (as defined in the [\*\*\*] Agreement) shall require, naming the [\*\*\*] Indemnitees as additional insureds. Such commercial general liability insurance shall provide: (i) product liability coverage and (ii) broad form contractual liability coverage for Sana's indemnification obligations under this Agreement.

- **(b)** If Sana elects to self-insure all or part of the limits described above in <u>Section 13.6(a)</u> (including deductibles or retentions that are in excess of \$[\*\*\*] annual aggregate) such self-insurance program must be acceptable to Beam, [\*\*\*] and the other Institutions and Federal Insurance Company (([\*\*\*]'s insurer) in their sole discretion. The minimum amounts of insurance coverage required shall not be construed to create a limit of Sana's liability with respect to its indemnification obligations under this Agreement.
- (c) Sana shall provide each Beam and Institution with written evidence of such insurance upon request of Beam or such Institution. Sana shall provide Beam and each Institution with written notice at least thirty (30) days prior to the cancellation, non-renewal or material change in such insurance. If Sana does not obtain replacement insurance providing comparable coverage within such thirty (30) day period, Beam shall have the right to terminate this Agreement effective at the end of such [\*\*\*] day period without notice or any additional waiting periods.
- **(d)** Sana shall maintain such commercial general liability insurance beyond the expiration or termination of this Agreement during: (a) the period that any Licensed Product is being commercially distributed or sold by Sana, or an Affiliate, Sublicensee or agent of Sana; and (b) a reasonable period after the period referred to in (a) above which in no event shall be less than [\*\*\*] years.
- 13.7 Limitation of Liability. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 13.7 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE (A) INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 13.1, 13.2 OR 13.3, OR (B) DAMAGES AVAILABLE FOR A PARTY'S BREACH OF ITS CONFIDENTIALITY OBLIGATIONS IN ARTICLE 10 OR USE OF BEAM TECHNOLOGY IN A MANNER OTHER THAN AS EXPRESSLY PERMITTED UNDER SECTION 2.1; OR (C) DAMAGES AVAILABLE FOR A PARTY'S GROSS NEGLIGENCE, INTENTIONAL MISCONDUCT OR FRAUD.

### ARTICLE 14 GENERAL PROVISIONS

**14.1 Force Majeure.** Neither Party shall be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation under this Agreement to the extent such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, potentially including embargoes, war, acts of war (whether war be declared or not), acts of terrorism, epidemics, pandemics, insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, fire, floods, earthquakes or other acts of God, or acts, generally applicable action or inaction by any governmental authority (but excluding any government action or inaction that is specific to such Party, its Affiliates or sublicensees, such as revocation or non-renewal of such Party's license to conduct business), or omissions or delays in acting by the other Party, or unavailability of materials

related to the manufacture of the Licensed Products or components thereof. The affected Party shall notify the other Party in writing of such force majeure circumstances as soon as reasonably practical, and shall promptly undertake and continue to use Commercially Reasonable Efforts to cure such force majeure circumstances or to perform its obligations in spite of the ongoing circumstances.

- Non-Solicitation.\_During the Term, each Party agrees that neither it nor any of its Affiliates will recruit, solicit, or induce any employee of the other Party that such Party knew [\*\*\*] to terminate his or her employment with such other Party and become employed by or consult for such Party, whether or not such employee is a full-time employee of such other Party, and whether or not such employment is pursuant to a written agreement or is at-will. For purposes of the foregoing, "recruit," "solicit," or "induce" will not be deemed to mean (a) circumstances where an employee of a Party (such employee, a "Soliciting Employee," and such Party, the "Existing Employer") (i) initiates contact with the other Party (the "Prospective Employer") or any of its Affiliates with regard to possible employment; or (ii) responds to general solicitations of employment not specifically targeted at employees of the Existing Employer or any of its Affiliates, including responses to general advertisements or postings (each of (i) and (ii), an "Employee-Initiated Solicitation"), and (b) discussions, interviews, negotiations, offers, or acceptances of employment or similar activities that arise as a result of circumstances described in the foregoing clause (a).
- 14.3 **Assignment.** This Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred, by either Party without the prior written consent of the other Party, and in the case of Sana, without the prior written consent of the [\*\*\*]. Notwithstanding the foregoing, either Party may, without consent of the other Party (or the [\*\*\*], in the case of assignment by Sana), assign or transfer this Agreement and its rights and obligations hereunder in whole or in part to an Affiliate of such Party, or in whole to its successor in interest in connection with the sale of all or substantially all of its stock or its assets to which this Agreement relates, or in connection with a merger, acquisition or similar transaction of the assigning Party, as long as such successor in interest agrees in writing to assume all of the assigning Party's obligations under this Agreement. In addition, either Party may, with the consent of the other Party (which shall not be unreasonably withheld), assign or transfer its rights and obligations under this Agreement to a Third Party (so long as such Third Party is not a direct competitor of the other Party) where such assigning Party or its Affiliate is required, or makes a good faith determination based on advice of counsel, to divest its rights in connection with a Licensed Product in order to comply with Law or the order of any Governmental Authority as a result of a merger or acquisition or similar transaction of the assigning Party, as long as such Third Party agrees in writing to assume all of the assigning Party's obligations under this Agreement. Any attempted assignment not in accordance with this <u>Section 14.3</u> shall be null and void and of no legal effect. Any permitted assignee shall assume in writing all assigned obligations of its assignor under this Agreement. The terms and conditions of this Agreement shall be binding upon, and shall inure to the benefit of, the Parties and their respected successors and permitted assigns. In the event of any assignment by a Party of this Agreement, such Party shall remain primarily liable to the other Party for the performance of this Agreement.

- **14.4 Severability.** If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of the Parties. The Parties shall in such an instance use their best efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) which, insofar as practical, implement the purposes of this Agreement.
- **14.5 Notices.** All notices which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

If to Beam:

Beam Therapeutics Inc. 26 Landsdowne Street Cambridge, MA 02139

Attn: Chief Legal Officer

Email: [\*\*\*]

with a copy to:

[\*\*\*]

[\*\*\*]

If to Sana:

Sana Biotechnology, Inc. 188 E Blaine Street, #400 Seattle, WA 98102

Attn: General Counsel

Email: Legal.Notices@sana.com

with a copy to:

[\*\*\*]

or to such other address(es) as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice shall be deemed to have been given: (a) on the Business Day when delivered if personally delivered or sent by facsimile on a Business Day (or if delivered or sent on a non-Business Day, then on the next Business Day); (b) on the Business Day after dispatch if sent by nationally-recognized overnight courier; or (c) on the [\*\*\*] Business Day following the date of mailing, if sent by mail.

- **14.6 Dispute Resolution**. The Parties recognize that disputes as to certain matters may from time to time arise that relate to either Party's rights and/or obligations hereunder, including the interpretation, alleged breach, enforcement, termination or validity of this Agreement (a "**Dispute**"). It is the objective of the Parties to establish procedures to facilitate the resolution of such Disputes arising under this Agreement in an expedient manner by mutual cooperation. To accomplish this objective, the Parties agree that if a Dispute arises under this Agreement, and the Parties are unable to resolve such Dispute within [\*\*\*] days after such Dispute is first identified by either Party in writing to the other, the Parties shall refer such Dispute to the Executive Officers of the Parties for attempted resolution by good faith negotiations within [\*\*\*] days after such notice is received. If the Executive Officers are not able to resolve such Dispute within [\*\*\*] days, then either Party shall be entitled to all available remedies, subject to Section 14.8. Notwithstanding the foregoing, and without waiting for the expiration of the time periods set forth above, each Party have the right to apply to any court of competent jurisdiction for appropriate interim or provisional relief, as necessary to protect its rights or property.
- **14.7 Governing Law.** This Agreement shall be governed by and construed in accordance with the laws of the State of New York, without reference to any rules of conflict of laws; provided that the United Nations Convention on Contracts for International Sale of Goods shall not apply.
- **Jurisdiction**. The Parties hereby irrevocably submit to the exclusive jurisdiction of the courts of the State 14.8 of New York and the Federal courts of the United States of America located in the State of New York, in respect of the interpretation and enforcement of the provisions of this Agreement and of the documents referred to herein, and in respect of the transactions hereby, and hereby waive, and agree not to assert, as a defense in any action, suit or proceeding for the interpretation or enforcement hereof or thereof, that it is not subject thereto or that such action, suit or proceeding may not be brought or is not maintainable in said courts or that the venue thereof may not be appropriate or that this Agreement or any such document may not be enforced in or by such courts, and the Parties irrevocably agree that all claims with respect to such action or proceeding shall be heard and determined in such a New York State or Federal court. The Parties hereby consent to and grant any such court jurisdiction over the person of such parties and over the subject matter of such dispute and agree that mailing of process or other papers in connection with any such action or proceeding in any manner as may be permitted by applicable Law, shall be valid and sufficient service thereof. With respect to any particular action, suit or proceeding, venue shall lie solely in United States District Court for the Southern District of New York located in New York City (or, if, and only if, such court does not have jurisdiction over the claim, the state courts of the State of New York located in New York City). A party hereto may apply either to a court of competent jurisdiction or to an arbitrator, if one has been appointed, for prejudgment remedies and emergency relief pending final determination of a claim pursuant to this Section 14.8.
- **14.9 Entire Agreement; Amendments.** This Agreement, together with the Exhibits hereto, contains the entire understanding of the Parties with respect to the subject matter hereof. Any other express or implied agreements and understandings, negotiations, writings and commitments, either oral or written, with respect to the subject matter hereof are superseded by the terms of this Agreement. This Agreement shall amend and supersede the Material Transfer

Agreement between the Parties dated [\*\*\*] (as amended, the "Prior MTA"), as follows: (a) Beam or Sana (as applicable) shall each have the right to use the Results in a manner consistent with the exercise of their respective rights under this Agreement; (b) Beam or Sana (as applicable) shall have the right to file Patent Rights Covering any inventions embodied in the Results, wherein such inventions (except for those solely related to the Company Materials) shall be considered Inventions under this Agreement; (c) disclosures made prior to the Effective Date pursuant to the Prior MTA shall be deemed to be Confidential Information and shall be subject to the confidentiality and non-use provisions of this Agreement; (d) Beam Materials (as defined therein) and information provided to Sana under the Prior MTA will be deemed provided pursuant to the Initial Technology Transfer Plan and subject to the rights and licenses in this Agreement; and (e) the Prior MTA will be deemed terminated as of the Effective Date, however, for clarity the payment obligations thereunder as it relates to Beam Materials transferred under the Prior MTA prior to the Effective Date will survive. The Exhibits to this Agreement are incorporated herein by reference and shall be deemed a part of this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representative(s) of both Parties hereto. The Parties agree that, effective as of the Effective Date, that certain Mutual Confidentiality Agreement between the Parties dated as of [\*\*\*] (the "Confidentiality Agreement") is hereby terminated by this Agreement, and that disclosures made prior to the Effective Date pursuant to the Confidentiality Agreements shall be deemed to be Confidential Information and shall be subject to the confidentiality and non-use provisions of this Agreement. For the purposes of this Section 14.9, the term "Company Materials" shall have the meaning set forth in the Prior MTA.

Third Party Beneficiary. Sana acknowledges and agrees that the [\*\*\*] is an intended third party beneficiary of this Agreement to the extent such this Agreement relates to a sublicense of the [\*\*\*] Patent Rights, solely for the purpose of (a) enforcing all patent challenge, intellectual property ownership, indemnification and insurance and compliance with law provisions of this Agreement, Exhibit D, and Exhibit F, in each case applicable to the [\*\*\*] Patent Rights (or the practice thereof) and, with respect to such indemnification and insurance provisions, Licensed Products, (b) enforcing the right to terminate such the licenses granted to Sana under the relevant [\*\*\*] Patent Rights for breach of the patent challenge, indemnification (solely with respect to Sana's obligation to indemnify the [\*\*\*]) and insurance provisions of this Agreement with respect to the relevant [\*\*\*] Patent Rights (or the practice thereof) and, with respect to such indemnification and insurance provisions, Licensed Products. Further, Sana acknowledges and agrees that (i) each of the President and Fellows of [\*\*\*] ("[\*\*\*]") and the [\*\*\*] ("[\*\*\*]") (collectively the "**Other Institutions**") are intended third party beneficiaries of this Agreement for the purpose of enforcing the Other Institutions' rights, including indemnification and insurance provisions that relate to the relevant [\*\*\*] Patent Rights (or the practice thereof) or Licensed Products under this Agreement, and (ii) (A) that the rights of the [\*\*\*] or any Other Institution may be enforced by the [\*\*\*] or any Other Institution in any court of competent jurisdiction and, without limiting the generality of the foregoing, Sana consents to jurisdiction in Massachusetts courts solely in connection with any such claim, and (B) notwithstanding the governing law of this Agreement, Sana agrees that, in the event of any difference in interpretation or result as between the laws of New York and the laws of Massachusetts, the laws of Massachusetts shall control in any action in which [\*\*\*] or any Other Institution is enforcing its rights under this Agreement.

- **14.11 Headings.** The captions to the several Articles, Sections and subsections hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the several Articles and Sections hereof.
- **14.12 Independent Contractors.** It is expressly agreed that Beam and Sana shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither Beam nor Sana shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party.
- **14.13 Waiver.** No provision of this Agreement will be waived by any act, omission or knowledge of a Party, its Affiliates or their respective agents or employees except by an instrument in writing expressly waiving such provision and signed by a duly authorized officer of the waiving Party. The waiver by either Party hereto of any right hereunder, or of any failure of the other Party to perform, or of any breach by the other Party, shall not be deemed a waiver of any other right hereunder or of any other breach by or failure of such other Party whether of a similar nature or otherwise.
- **14.14 Cumulative Remedies.** No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.
- **14.15 Waiver of Rule of Construction.** Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.
- **14.16 Business Day Requirements.** If any notice or other action or omission is required to be taken by a Party under this Agreement on a day that is not a Business Day then such notice or other action or omission shall be deemed to be required to be taken on the next occurring Business Day.
- **14.17 Translations.** This Agreement is in the English language only, which language shall be controlling in all respects, and all versions hereof in any other language shall be for accommodation only and shall not be binding upon the Parties. All communications and notices to be made or given pursuant to this Agreement, and any dispute proceeding related to or arising hereunder, shall be in the English language. If there is a discrepancy between any translation of this Agreement and this Agreement, this Agreement shall prevail.
- **14.18 Further Actions.** Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as necessary or appropriate in order to carry out the purposes and intent of this Agreement.
- **14.19 Counterparts.** This Agreement may be executed in two or more counterparts by original signature, facsimile or PDF files, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

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IN WITNESS WHEREOF, the Parties intending to be bound have caused this Option and License Agreement to be executed by their duly authorized representatives as of the Effective Date.

Beam Therapeutics Inc. Sana Biotechnology, Inc.

By:/s/ John Evans By:/s/ Steve Harr, M.D.

Name:John Evans Name:Steve Harr, M.D.

Title:Chief Executive Officer Title:CEO

## LIST OF EXHIBITS

**Beam Patents as of the Effective Date** Exhibit A:

**Existing Third Party Licenses Exhibit B:** 

**Genetic Target List Exhibit C:** 

**Certain Terms of Third Party Licenses Exhibit D:** 

**Exhibit E:** 

Initial Technology Transfer
Third Party Pass Through Milestone and Royalty Terms **Exhibit F:** 

**Wiring Instructions Exhibit G:** 

# Exhibit A

## **Beam Patents as of the Effective Date**

[\*\*\*]

A-1

# Exhibit B

# **Existing Third Party Licenses**

[\*\*\*]

B-1

# **Exhibit C**

# **Genetic Target List**

[\*\*\*]

C-1

# Exhibit D

# **Third Party License Terms**

[\*\*\*]

D-1

# Exhibit E

# **Initial Technology Transfer and Budget**

[\*\*\*]

G-1

# Exhibit G

# **Wiring Instructions**

[\*\*\*]

G-2

#### SANA BIOTECHNOLOGY, INC.

### 2018 EQUITY INCENTIVE PLAN

(Revised November 2, 2018)

## 1. <u>Purpose</u>.

The purpose of the Plan is to advance the interests of the Company's stockholders by enhancing the Company's ability to attract, retain and motivate persons who make (or are expected to make) important contributions to the Company by providing such persons with equity ownership opportunities and thereby better aligning the interests of such persons with those of the Company's stockholders. Capitalized terms used in the Plan are defined in Section 11 below.

## 2. <u>Eligibility</u>.

Service Providers are eligible to be granted Awards under the Plan, subject to the limitations described herein.

## 3. <u>Administration and Delegation</u>.

- Administration. The Plan will be administered by the Administrator. The Administrator shall have authority to determine which Service Providers will receive Awards, to grant Awards and to set all terms and conditions of Awards (including, but not limited to, vesting, exercise and forfeiture provisions). In addition, the Administrator shall have the authority to take all actions and make all determinations contemplated by the Plan and to adopt, amend and repeal such administrative rules, guidelines and practices relating to the Plan as it shall deem advisable. The Administrator may correct any defect or ambiguity, supply any omission or reconcile any inconsistency in the Plan or any Award in the manner and to the extent it shall deem necessary or appropriate to carry the Plan and any Awards into effect, as determined by the Administrator. The Administrator shall make all determinations under the Plan in the Administrator's sole discretion and all such determinations shall be final and binding on all persons having or claiming any interest in the Plan or in any Award.
- 3.2 <u>Appointment of Committees</u>. To the extent permitted by Applicable Laws, the Board may delegate any or all of its powers under the Plan to one or more Committees. The Board may abolish any Committee at any time and revest in itself any previously delegated authority.

#### 4. Stock Available for Awards.

4.1 <u>Number of Shares</u>. Subject to adjustment under Section 8 hereof, Awards may be made under the Plan covering up to 27,300,000 shares of Common Stock. If any Award expires or lapses or is terminated, surrendered or canceled without having been fully exercised or is forfeited in whole or in part (including as the result of shares of Common Stock subject to such Award being repurchased by the Company at or below the original issuance price), in any case in a manner that results in any shares of Common Stock covered by such Award not being issued or

being so reacquired by the Company, the unused Common Stock covered by such Award shall again be available for the grant of Awards under the Plan. Further, shares of Common Stock delivered (either by actual delivery or attestation) to the Company by a Participant to satisfy the applicable exercise or purchase price of an Award and/or to satisfy any applicable tax withholding obligation (including shares retained by the Company from the Award being exercised or purchased and/or creating the tax obligation) shall be added to the number of shares of Common Stock available for the grant of Awards under the Plan. However, in the case of Incentive Stock Options (as hereinafter defined), the foregoing provisions shall be subject to any limitations under the Code. Shares of Common Stock issued under the Plan may consist in whole or in part of authorized but unissued shares, shares purchased on the open market or treasury shares.

4.2 <u>Substitute Awards</u>. In connection with a merger or consolidation of an entity with the Company or the acquisition by the Company of property or stock of an entity, the Administrator may grant Awards in substitution for any options or other stock or stock-based awards granted prior to such merger or consolidation by such entity or an affiliate thereof. Substitute Awards may be granted on such terms as the Administrator deems appropriate in the circumstances, notwithstanding any limitations on Awards contained in the Plan. Substitute Awards shall not count against the overall share limit set forth in Section 4.1 hereof, except as may be required by reason of Section 422 of the Code.

## 5. <u>Stock Options</u>.

- 5.1 <u>General</u>. The Administrator may grant Options to any Service Provider, subject to the limitations on Incentive Stock Options described below. The Administrator shall determine the number of shares of Common Stock to be covered by each Option, the exercise price of each Option and the conditions and limitations applicable to the exercise of each Option, including conditions relating to Applicable Laws, as it considers necessary or advisable.
- 5.2 <u>Incentive Stock Options</u>. The Administrator may grant Options intended to qualify as Incentive Stock Options only to employees of the Company, any of the Company's present or future "parent corporations" or "subsidiary corporations" as defined in Sections 424(e) or (f) of the Code, respectively, and any other entities the employees of which are eligible to receive Incentive Stock Options under the Code. All Options intended to qualify as Incentive Stock Options shall be subject to and shall be construed consistently with the requirements of Section 422 of the Code. Neither the Company nor the Administrator shall have any liability to a Participant, or any other party, (i) if an Option (or any part thereof) which is intended to qualify as an Incentive Stock Option or (ii) for any action or omission by the Administrator that causes an Option not to qualify as an Incentive Stock Option, including without limitation, the conversion of an Incentive Stock Option to a Non-Qualified Stock Option or the grant of an Option intended as an Incentive Stock Option that fails to satisfy the requirements under the Code applicable to an Incentive Stock Option. Any Option that is intended to qualify as an Incentive Stock Option, but fails to so qualify for any reason, including without limitation, the portion of any Option becoming exercisable in excess of the \$100,000 limitation described in Treasury Regulation Section 1.422-4, shall be treated as a Non-Qualified Stock Option for all purposes.

- 5.3 Exercise Price. The Administrator shall establish the exercise price of each Option and specify the exercise price in the applicable Award Agreement. The exercise price shall be not less than 100% of the Fair Market Value on the date the Option is granted. In the case of an Incentive Stock Option granted to an employee who, at the time of grant of the Option, owns (or is treated as owning under Section 424 of the Code) stock representing more than 10% of the voting power of all classes of stock of the Company (or a "parent corporation" or "subsidiary corporation" thereof within the meaning of Sections 424(e) or 424(f) of the Code, respectively), the per share exercise price shall be no less than 110% of the Fair Market Value on the date the Option is granted.
- 5.4 <u>Duration of Options</u>. Each Option shall be exercisable at such times and subject to such terms and conditions as the Administrator may specify in the applicable Award Agreement, <u>provided that</u> the term of any Option shall not exceed ten years. In the case of an Incentive Stock Option granted to an employee who, at the time of grant of the Option, owns (or is treated as owning under Section 424 of the Code) stock representing more than 10% of the voting power of all classes of stock of the Company (or a "parent corporation" or "subsidiary corporation" thereof within the meaning of Sections 424(e) or 424(f) of the Code, respectively), the term of the Option shall not exceed five years.
- 5.5 Exercise of Option; Notification of Disposition. Options may be exercised by delivery to the Company of a written notice of exercise, in a form approved by the Administrator (which may be an electronic form), signed by the person authorized to exercise the Option, together with payment in full (i) as specified in Section 5.6 hereof for the number of shares for which the Option is exercised and (ii) as specified in Section 9.5 hereof for any applicable withholding taxes. Unless otherwise determined by the Administrator, an Option may not be exercised for a fraction of a share of Common Stock. If an Option is designated as an Incentive Stock Option, the Participant shall give prompt notice to the Company of any disposition or other transfer of any shares of Common Stock acquired from the Option if such disposition or transfer is made (i) within two years from the grant date with respect to such Option or (ii) within one year after the transfer of such shares to the Participant (other than any such disposition made in connection with a Change in Control). Such notice shall specify the date of such disposition or other transfer and the amount realized, in cash, other property, assumption of indebtedness or other consideration, by the Participant in such disposition or other transfer.
- 5.6 <u>Payment Upon Exercise</u>. Common Stock purchased upon the exercise of an Option granted under the Plan shall be paid for in cash or by check, payable to the order of the Company, or, to the extent permitted by the Administrator, by:
- (a) (A) delivery of an irrevocable and unconditional undertaking by a broker acceptable to the Company to deliver promptly to the Company sufficient funds to pay the exercise price and any required tax withholding, or (B) delivery by the Participant to the Company of a copy of irrevocable and unconditional instructions to a broker acceptable to the Company to deliver promptly to the Company cash or a check sufficient to pay the exercise price and any required tax withholding;
- (b) delivery (either by actual delivery or attestation) of shares of Common Stock owned by the Participant valued at their Fair Market Value, provided (A) such

method of payment is then permitted under Applicable Laws, (B) such Common Stock, if acquired directly from the Company, was owned by the Participant for such minimum period of time, if any, as may be established by the Company at any time, and (C) such Common Stock is not subject to any repurchase, forfeiture, unfulfilled vesting or other similar requirements;

- (c) surrendering shares of Common Stock then issuable upon exercise of the Option valued at their Fair Market Value on the date of exercise;
- (d) delivery of a promissory note of the Participant to the Company on terms determined by the Administrator;
- (e) delivery of property of any other kind which constitutes good and valuable consideration as determined by the Administrator; or
  - (f) any combination of the above permitted forms of payment (including cash or check).
- 5.7 <u>Early Exercise of Options</u>. The Administrator may provide in the terms of an Award Agreement that the Service Provider may exercise an Option in whole or in part prior to the full vesting of the Option in exchange for unvested shares of Restricted Stock with respect to any unvested portion of the Option so exercised. Shares of Restricted Stock acquired upon the exercise of any unvested portion of an Option shall be subject to such terms and conditions as the Administrator shall determine.

### 6. Restricted Stock; Restricted Stock Units.

- General. The Administrator may grant Restricted Stock, or the right to purchase Restricted Stock, to any Service Provider, subject to the right of the Company to repurchase all or part of such shares at their issue price or other stated or formula price from the Participant (or to require forfeiture of such shares if issued at no cost) in the event that conditions specified by the Administrator in the applicable Award Agreement are not satisfied prior to the end of the applicable restriction period or periods established by the Administrator for such Award. In addition, the Administrator may grant to Service Providers Restricted Stock Units, which may be subject to vesting and forfeiture conditions during applicable restriction period or periods, as set forth in an applicable Award Agreement.
- 6.2 Terms and Conditions for All Restricted Stock and Restricted Stock Unit Awards. The Administrator shall determine and set forth in the applicable Award Agreement the terms and conditions applicable to each Restricted Stock and Restricted Stock Unit Award, including the conditions for vesting and repurchase (or forfeiture) and the issue price, in each case, if any.

## 6.3 <u>Additional Provisions Relating to Restricted Stock.</u>

(a) *Dividends*. Participants holding shares of Restricted Stock will be entitled to all ordinary cash dividends paid with respect to such shares to the extent such dividends have a record date that is on or after the date on which the Participant to whom such Restricted Shares are granted becomes the record holder of such Restricted Shares, unless otherwise provided

by the Administrator in the applicable Award Agreement. In addition, unless otherwise provided by the Administrator, if any dividends or distributions are paid in shares, or consist of a dividend or distribution to holders of Common Stock of property other than an ordinary cash dividend, the shares or other property will be subject to the same restrictions on transferability and forfeitability as the shares of Restricted Stock with respect to which they were paid. Each dividend payment will be made as provided in the applicable Award Agreement, but in no event later than the end of the calendar year in which the dividends are paid to stockholders of that class of stock or, if later, the 15th day of the third month following the later of (A) the date the dividends are paid to stockholders of that class of stock, and (B) the date the dividends are no longer subject to forfeiture.

(b) *Stock Certificates*. The Company may require that any stock *certificates* issued in respect of shares of Restricted Stock be deposited in escrow by the Participant, together with a stock power endorsed in blank, with the Company (or its designee).

## 6.4 <u>Additional Provisions Relating to Restricted Stock Units.</u>

- (a) *Settlement*. Upon the vesting of a Restricted Stock Unit, the Participant *shall* be entitled to receive from the Company one share of Common Stock or an amount of cash or other property equal to the Fair Market Value of one share of Common Stock on the settlement date, as the Administrator shall determine and as provided in the applicable Award Agreement. The Administrator may provide that settlement of Restricted Stock Units shall occur upon or as soon as reasonably practicable after the vesting of the Restricted Stock Units or shall instead be deferred, on a mandatory basis or at the election of the Participant, in a manner that complies with Section 409A.
- (b) *Voting Rights*. A Participant shall have no voting rights with respect to any Restricted Stock Units unless and until shares are delivered in settlement thereof.
- (c) *Dividend Equivalents*. To the extent provided by the Administrator, a grant of Restricted Stock Units may provide a Participant with the right to receive Dividend Equivalents. Dividend Equivalents may be paid currently or credited to an account for the Participant, may be settled in cash and/or shares of Common Stock and may be subject to the same restrictions on transfer and forfeitability as the Restricted Stock Units with respect to which the Dividend Equivalents are paid, as determined by the Administrator, subject, in each case, to such terms and conditions as the Administrator shall establish and set forth in the applicable Award Agreement.

## 7. Other Stock-Based Awards.

Other Stock-Based Awards may be granted hereunder to Participants, including, without limitation, Awards entitling Participants to receive shares of Common Stock to be delivered in the future. Such Other Stock-Based Awards shall also be available as a form of payment in the settlement of other Awards granted under the Plan, as stand-alone payments and/or as payment in lieu of compensation to which a Participant is otherwise entitled. Other Stock-Based Awards may be paid in shares of Common Stock, cash or other property, as the Administrator shall determine. Subject to the provisions of the Plan, the Administrator shall determine the terms and conditions of each Other Stock-Based Award, including any purchase price, transfer restrictions,

vesting conditions and other terms and conditions applicable thereto, which shall be set forth in the applicable Award Agreement.

#### 8. Adjustments for Changes in Common Stock and Certain Other Events.

- 8.1 In the event that the Administrator determines that any dividend or other distribution (whether in the form of cash, Common Stock, other securities, or other property), reorganization, merger, consolidation, combination, repurchase, recapitalization, liquidation, dissolution, or sale, transfer, exchange or other disposition of all or substantially all of the assets of the Company, or sale or exchange of Common Stock or other securities of the Company, issuance of warrants or other rights to purchase Common Stock or other securities of the Company, or other similar corporate transaction or event, as determined by the Administrator, affects the Common Stock such that an adjustment is determined by the Administrator to be appropriate in order to prevent dilution or enlargement of the benefits or potential benefits intended by the Company to be made available under the Plan or with respect to any Award, then the Administrator may, in such manner as it may deem equitable, adjust any or all of:
- (a) the number and kind of shares of Common Stock (or other securities or property) with respect to which Awards may be granted or awarded (including, but *not* limited to, adjustments of the limitations in Section 4 hereof on the maximum number and kind of shares which may be issued);
- (b) the number and kind of shares of Common Stock (or other securities or property) subject to outstanding Awards;
  - (c) the grant or exercise price with respect to any Award; and
- (d) the terms and conditions of any Awards (including, without limitation, any applicable financial or other performance "targets" specified in an Award Agreement).
- 8.2 In the event of any transaction or event described in Section 8.1 hereof (including without limitation any Change in Control) or any unusual or nonrecurring transaction or event affecting the Company or the financial statements of the Company, or any change in any Applicable Laws or accounting principles, the Administrator, on such terms and conditions as it deems appropriate, either by the terms of the Award or by action taken prior to the occurrence of such transaction or event and either automatically or upon the Participant's request, is hereby authorized to take any one or more of the following actions whenever the Administrator determines that such action is appropriate in order to (x) prevent dilution or enlargement of the benefits or potential benefits intended by the Company to be made available under the Plan or with respect to any Award granted or issued under the Plan, (y) to facilitate such transaction or event or (z) give effect to such changes in Applicable Laws or accounting principles:
- (a) To provide for the cancellation of any such Award in exchange for either an amount of cash or other property with a value equal to the amount that could have been obtained upon the exercise or settlement of the vested portion of such Award or realization of the Participant's rights under the vested portion of such Award, as applicable; provided that, if the amount that could have been obtained upon the exercise or settlement of the vested portion of such

Award or realization of the Participant's rights, in any case, is equal to or less than zero, then the vested portion of such Award may be terminated without payment;

- (b) To provide that such Award shall vest and, to the extent applicable, be exercisable as to all shares covered thereby, notwithstanding anything to the contrary in the Plan or the provisions of such Award;
- (c) To provide that such Award be assumed by the successor or survivor corporation, or a parent or subsidiary thereof, or shall be substituted for by awards covering the stock of the successor or survivor corporation, or a parent or subsidiary thereof, with appropriate adjustments as to the number and kind of shares and applicable exercise or purchase price, in all cases, as determined by the Administrator;
- (d) To make adjustments in the number and type of shares of Common Stock (or other securities or property) subject to outstanding Awards, and/or in the terms and conditions of (including the grant or exercise price), and the criteria included in, outstanding Awards which may be granted in the future;
  - (e) To replace such Award with other rights or property selected by the Administrator; and/or
- (f) To provide that the Award will terminate and cannot vest, be exercised or become payable after the applicable event.
- Notwithstanding the provisions of Section 8.2 above, if a Change in Control occurs and a Participant's Awards are not continued, converted, assumed, or replaced with a substantially similar award by (i) the Company, or (ii) a successor entity or its parent or subsidiary (an "Assumption"), and provided that the Participant has not had a Termination of Service, then immediately prior to the Change in Control such Awards shall become fully vested, exercisable and/or payable, as applicable, and all forfeiture, repurchase and other restrictions on such Awards shall lapse, in which case, such Awards shall be canceled upon the consummation of the Change in Control in exchange for the right to receive the Change in Control consideration payable to other holders of Common Stock (A) which may be on such terms and conditions as apply generally to holders of Common Stock under the Change in Control documents (including, without limitation, any escrow, earn-out or other deferred consideration provisions) or such other terms and conditions as the Administrator may provide, and (B) determined by reference to the number of shares subject to such Awards and net of any applicable exercise price; provided that to the extent that any Awards constitute "nonqualified deferred compensation" that may not be paid upon the Change in Control under Section 409A without the imposition of taxes thereon under Section 409A, the timing of such payments shall be governed by the applicable Award Agreement (subject to any deferred consideration provisions applicable under the Change in Control documents); and provided, further, that if the amount to which a Participant would be entitled upon the settlement or exercise of such Award at the time of the Change in Control is equal to or less than zero, then such Award may be terminated without payment. The Administrator shall determine whether an Assumption of an Award has occurred in connection with a Change in Control.

- 8.4 In connection with the occurrence of any Equity Restructuring, and notwithstanding anything to the contrary in this Section 8, the Administrator will equitably adjust each outstanding Award, which adjustments may include adjustments to the number and type of securities subject to each outstanding Award and/or the exercise price or grant price thereof, if applicable, the grant of new Awards to Participants, and/or the making of a cash payment to Participants, as the Administrator deems appropriate to reflect such Equity Restructuring. The adjustments provided under this Section 8.4 shall be nondiscretionary and shall be final and binding on the affected Participant and the Company; provided that whether an adjustment is equitable shall be determined by the Administrator.
- 8.5 In the event of any pending stock dividend, stock split, combination or exchange of shares, merger, consolidation or other distribution (other than normal cash dividends) of Company assets to stockholders, or any other change affecting the shares of Common Stock or the share price of the Common Stock, including any Equity Restructuring, for reasons of administrative convenience the Administrator may refuse to permit the exercise of any Award during a period of up to thirty days prior to the consummation of any such transaction.
- 8.6 Except as expressly provided in the Plan or pursuant to action of the Administrator under the Plan, no Participant shall have any rights by reason of any subdivision or consolidation of shares of stock of any class, the payment of any dividend, any increase or decrease in the number of shares of stock of any class or any dissolution, liquidation, merger, or consolidation of the Company or any other corporation. Except as expressly provided in the Plan or pursuant to action of the Administrator under the Plan, no issuance by the Company of shares of stock of any class, or securities convertible into shares of stock of any class, shall affect, and no adjustment by reason thereof shall be made with respect to, the number of shares of Common Stock subject to an Award or the grant or exercise price of any Award. The existence of the Plan, any Award Agreements and the Awards granted hereunder shall not affect or restrict in any way the right or power of the Company to make or authorize (i) any adjustment, recapitalization, reorganization or other change in the Company's capital structure or its business, (ii) any merger, consolidation dissolution or liquidation of the Company or sale of Company assets or (iii) any sale or issuance of securities, including without limitation, securities with rights superior to those of the Common Stock or which are convertible into or exchangeable for Common Stock. The Administrator may treat Participants and Awards (or portions thereof) differently under this Section 8.

## 9. <u>General Provisions Applicable to Awards</u>.

9.1 <u>Transferability</u>. Except as the Administrator may otherwise determine or provide in an Award Agreement or otherwise, in any case in accordance with Applicable Laws, Awards shall not be sold, assigned, transferred, pledged or otherwise encumbered by the person to whom they are granted, either voluntarily or by operation of law, except by will or the laws of descent and distribution, and, during the life of the Participant, shall be exercisable only by the Participant. References to a Participant, to the extent relevant in the context, shall include references to authorized transferees.

- 9.2 <u>Documentation</u>. Each Award shall be evidenced in an Award Agreement, which may be in such form (written, electronic or otherwise) as the Administrator shall determine. Each Award may contain terms and conditions in addition to those set forth in the Plan.
- 9.3 <u>Discretion</u>. Except as otherwise provided by the Plan, each Award may be made alone or in addition or in relation to any other Award. The terms of each Award to a Participant need not be identical, and the Administrator need not treat Participants or Awards (or portions thereof) uniformly.
- 9.4 <u>Termination of Status</u>. The Administrator shall determine the effect on an Award of the disability, death, retirement, authorized leave of absence or any other change or purported change in a Participant's Service Provider status and the extent to which, and the period during which, the Participant, the Participant's legal representative, conservator, guardian or Designated Beneficiary may exercise rights under the Award, if applicable.
- 9.5 <u>Withholding</u>. Each Participant shall pay to the Company, or make provision satisfactory to the Administrator for payment of, any taxes required by law to be withheld in connection with Awards to such Participant no later than the date of the event creating the tax liability. Except as the Administrator may otherwise determine, all such payments shall be made in cash or by certified check. Notwithstanding the foregoing, to the extent permitted by the Administrator, Participants may satisfy such tax obligations in whole or in part by delivery of shares of Common Stock, including shares retained from the Award creating the tax obligation, valued at their Fair Market Value. The Company may, to the extent permitted by Applicable Laws, deduct any such tax obligations from any payment of any kind otherwise due to a Participant.
- 9.6 <u>Amendment of Award</u>. The Administrator may amend, modify or terminate any outstanding Award, including but not limited to, substituting therefor another Award of the same or a different type, changing the date of exercise or settlement, and converting an Incentive Stock Option to a Non-Qualified Stock Option. The Participant's consent to such action shall be required unless (i) the Administrator determines that the action, taking into account any related action, would not materially and adversely affect the Participant, or (ii) the change is permitted under Section 8 and 10.6 hereof.
- 9.7 <u>Conditions on Delivery of Stock.</u> The Company will not be obligated to deliver any shares of Common Stock pursuant to the Plan or to remove restrictions from shares previously delivered under the Plan until (i) all conditions of the Award have been met or removed to the satisfaction of the Company, (ii) in the opinion of the Company's counsel, all other legal matters in connection with the issuance and delivery of such shares have been satisfied, including any applicable securities laws and any applicable stock exchange or stock market rules and regulations, and (iii) the Participant has executed and delivered to the Company such representations or agreements as the Administrator deems necessary or appropriate to satisfy the requirements of any Applicable Laws. The inability of the Company to obtain authority from any regulatory body having jurisdiction, which authority is determined by the Administrator to be necessary to the lawful issuance and sale of any securities hereunder, shall relieve the Company of any liability in respect of the failure to issue or sell such shares as to which such requisite authority shall not have been obtained.

9.8 <u>Acceleration</u>. The Administrator may at any time provide that any Award shall become immediately vested and/or exercisable in full or in part, free of some or all restrictions or conditions, or otherwise realizable in full or in part, as the case may be.

#### 10. Miscellaneous.

- 10.1 No Right To Employment or Other Status. No person shall have any claim or right to be granted an Award, and the grant of an Award shall not be construed as giving a Participant the right to continued employment or any other relationship with the Company. The Company expressly reserves the right at any time to dismiss or otherwise terminate its relationship with a Participant free from any liability or claim under the Plan or any Award, except as expressly provided in an applicable Award Agreement.
- 10.2 <u>No Rights As Stockholder; Certificates</u>. Subject to the provisions of the applicable Award Agreement, no Participant or Designated Beneficiary shall have any rights as a stockholder with respect to any shares of Common Stock to be distributed with respect to an Award until becoming the record holder of such shares. Notwithstanding any other provision of the Plan, unless otherwise determined by the Administrator or required by any Applicable Laws, the Company shall not be required to deliver to any Participant certificates evidencing shares of Common Stock issued in connection with any Award and instead such shares of Common Stock may be recorded in the books of the Company (or, as applicable, its transfer agent or stock plan administrator). The Company may place legends on any stock certificates issued under the Plan deemed necessary or appropriate by the Administrator in order to comply with Applicable Laws.
- 10.3 Effective Date and Term of Plan. The Plan shall become effective on the date on which it is adopted by the Board. No Awards shall be granted under the Plan after the completion of ten years from the earlier of (i) the date on which the Plan was adopted by the Board or (ii) the date the Plan was approved by the Company's stockholders, but Awards previously granted may extend beyond that date in accordance with the terms of the Plan.
- Amendment of Plan. The Administrator may amend, suspend or terminate the Plan or any portion thereof at any time; <u>provided that</u> no amendment of the Plan shall materially and adversely affect any Award outstanding at the time of such amendment without the consent of the affected Participant. Awards outstanding under the Plan at the time of any suspension or termination of the Plan shall continue to be governed in accordance with the terms of the Plan and the applicable Award Agreement, as in effect prior to such suspension or termination. The Board shall obtain stockholder approval of any Plan amendment to the extent necessary to comply with Applicable Laws.
- 10.5 <u>Provisions for Foreign Participants</u>. The Administrator may modify Awards granted to Participants who are foreign nationals or employed outside the United States or establish subplans or procedures under the Plan to address differences in laws, rules, regulations or customs of such foreign jurisdictions with respect to tax, securities, currency, employee benefit or other matters.

### 10.6 <u>Section 409A</u>.

- (a) General. The Company intends that all Awards be structured in compliance with, or to satisfy an exemption from, Section 409A, such that no adverse tax consequences, interest, or penalties under Section 409A apply in connection with any Awards. Notwithstanding anything herein or in any Award Agreement to the contrary, the Administrator may, without a Participant's prior consent, amend this Plan and/or Awards, adopt policies and procedures, or take any other actions (including amendments, policies, procedures and actions with retroactive effect) as are necessary or appropriate to preserve the intended tax treatment of Awards under the Plan, including without limitation, any such actions intended to (A) exempt this Plan and/or any Award from the application of Section 409A, and/or (B) comply with the requirements of Section 409A, including without limitation any such regulations, guidance, compliance programs and other interpretative authority that may be issued after the date of grant of any Award. The Company makes no representations or warranties as to the tax treatment of any Award under Section 409A or otherwise. The Company shall have no obligation under this Section 10.6 or otherwise to take any action (whether or not described herein) to avoid the imposition of taxes, penalties or interest under Section 409A with respect to any Award and shall have no liability to any Participant or any other person if any Award, compensation or other benefits under the Plan are determined to constitute non-compliant, "nonqualified deferred compensation" subject to the imposition of taxes, penalties and/or interest under Section 409A.
- (b) Separation from Service. With respect to any Award that constitutes "nonqualified deferred compensation" under Section 409A, any payment or settlement of such Award that is to be made upon a termination of a Participant's Service Provider relationship shall, to the extent necessary to avoid the imposition of taxes under Section 409A, be made only upon the Participant's "separation from service" (within the meaning of Section 409A), whether such "separation from service" occurs upon or subsequent to the termination of the Participant's Service Provider relationship. For purposes of any such provision of this Plan or any Award Agreement relating to any such payments or benefits, references to a "termination," "termination of employment" or like terms shall mean "separation from service."
- (c) Payments to Specified Employees. Notwithstanding any contrary provision in the Plan or any Award Agreement, any payment(s) of "nonqualified deferred compensation" that are otherwise required to be made under an Award to a "specified employee" (as defined under Section 409A and determined by the Administrator) as a result of his or her "separation from service" shall, to the extent necessary to avoid the imposition of taxes under Code Section 409A(a)(2)(B)(i), be delayed until the expiration of the six-month period immediately following such "separation from service" (or, if earlier, until the date of death of the specified employee) and shall instead be paid (in a manner set forth in the Award agreement) on the day that immediately follows the end of such six-month period or as soon as administratively practicable thereafter (without interest). Any payments of "nonqualified deferred compensation" under such Award that are, by their terms, payable more than six months following the Participant's "separation from service" shall be paid at the time or times such payments are otherwise scheduled to be made.
- 10.7 <u>Limitations on Liability</u>. Notwithstanding any other provisions of the Plan, no individual acting as a director, officer, other employee or agent of the Company will be liable

to any Participant, former Participant, spouse, beneficiary, or any other person for any claim, loss, liability, or expense incurred in connection with the Plan or any Award, nor will such individual be personally liable with respect to the Plan because of any contract or other instrument he or she executes in his or her capacity as an Administrator, director, officer, other employee or agent of the Company. The Company will indemnify and hold harmless each director, officer, other employee and agent of the Company to whom any duty or power relating to the administration or interpretation of the Plan has been or will be granted or delegated, against any cost or expense (including attorneys' fees) or liability (including any sum paid in settlement of a claim with the Administrator's approval) arising out of any act or omission to act concerning this Plan unless arising out of such person's own fraud or bad faith.

Lock-Up Period. Participants shall not offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any Common Stock (or other securities) of the Company or enter into any swap, hedging or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of any Common Stock (or other securities) of the Company held by Participant (other than those included in the registration) for a period specified by the representative of the underwriters of Common Stock (or other securities) of the Company not to exceed one hundred and eighty (180) days following the effective date of any registration statement of the Company filed under the Securities Act (or such other period as may be requested by the Company or the underwriters to accommodate regulatory restrictions on (i) the publication or other distribution of research reports and (ii) analyst recommendations and opinions, including, but not limited to, the restrictions contained in FINRA Rule 2241, or any successor provisions or amendments thereto). Participants shall execute and deliver such other agreements as may be reasonably requested by the Company or the underwriter which are consistent with the foregoing or which are necessary to give further effect thereto. The obligations described in this Section 10.8 shall not apply to a registration relating solely to employee benefit plans on Form S-1 or Form S-8 or similar forms that may be promulgated in the future, or a registration relating solely to a Securities and Exchange Commission Rule 145 transaction on Form S-4 or similar forms that may be promulgated in the future. The Company may impose stop-transfer instructions with respect to the shares of Common Stock (or other securities) subject to the foregoing restriction until the end of said 180 day (or other) period.

Limitations on Transfer. A Participant shall not sell, assign, transfer, pledge, hypothecate or otherwise dispose of, by operation of law or otherwise (collectively "Transfer") any interest in any shares of Common Stock held by Participant except in compliance with the provisions herein, in the Company's Bylaws and applicable securities laws. Furthermore, the shares of Common Stock shall be subject to a right of first refusal in favor of the Company or its assignees as set forth in the Company's Bylaws. Notwithstanding the foregoing, Participant may, subject to compliance with the transfer restrictions set forth in the Company's Bylaws, transfer shares of Common Stock to or for the benefit of any spouse, children, parents, uncles, aunts, siblings, grandchildren and any other relatives approved by the Board of Directors (collectively, "Approved Relatives") or to a trust established solely for the benefit of the Participant and/or Approved Relatives, provided that such shares of Common Stock shall remain subject to the provisions of this Plan and any other applicable agreements, and such permitted transferee shall, as a condition to such transfer, deliver to the Company a written instrument confirming that such

transferee shall be bound by all of the terms and conditions of this Plan and any other applicable agreements. The Company shall not be required (a) to transfer on its books any of the shares of Common Stock that have been sold or otherwise transferred in violation of any of the provisions of this Plan, any other applicable agreement or the provisions of the Company's Bylaws or (b) to treat as owner of such shares of Common Stock or to accord the right to vote or pay dividends to any purchaser or other transferee to whom any such shares of Common Stock shall have been so sold or transferred.

Data Privacy. As a condition of receipt of any Award, each Participant explicitly and 10.10 unambiguously consents to the collection, use and transfer, in electronic or other form, of personal data as described in this paragraph by and among, as applicable, the Company and its subsidiaries and affiliates for the exclusive purpose of implementing, administering and managing the Participant's participation in the Plan. The Company and its subsidiaries and affiliates may hold certain personal information about a Participant, including but not limited to, the Participant's name, home address and telephone number, date of birth, social security or insurance number or other identification number, salary, nationality, job title(s), any shares of stock held in the Company or any of its subsidiaries and affiliates, details of all Awards, in each case, for the purpose of implementing, managing and administering the Plan and Awards (the "Data"). The Company and its subsidiaries and affiliates may transfer the Data amongst themselves as necessary for the purpose of implementation, administration and management of a Participant's participation in the Plan, and the Company and its subsidiaries and affiliates may each further transfer the Data to any third parties assisting the Company in the implementation, administration and management of the Plan. These recipients may be located in the Participant's country, or elsewhere, and the Participant's country may have different data privacy laws and protections than the recipients' country. Through acceptance of an Award, each Participant authorizes such recipients to receive, possess, use, retain and transfer the Data, in electronic or other form, for the purposes of implementing, administering and managing the Participant's participation in the Plan, including any requisite transfer of such Data as may be required to a broker or other third party with whom the Company or the Participant may elect to deposit any shares of Common Stock. The Data related to a Participant will be held only as long as is necessary to implement, administer, and manage the Participant's participation in the Plan, A Participant may, at any time, view the Data held by the Company with respect to such Participant, request additional information about the storage and processing of the Data with respect to such Participant, recommend any necessary corrections to the Data with respect to the Participant or refuse or withdraw the consents herein in writing, in any case without cost, by contacting his or her local human resources representative. The Company may cancel Participant's ability to participate in the Plan and, in the Administrator's discretion, the Participant may forfeit any outstanding Awards if the Participant refuses or withdraws his or her consents as described herein. For more information on the consequences of refusal to consent or withdrawal of consent, Participants may contact their local human resources representative.

10.11 <u>Severability</u>. In the event any portion of the Plan or any action taken pursuant thereto shall be held illegal or invalid for any reason, the illegality or invalidity shall not affect the remaining parts of the Plan, and the Plan shall be construed and enforced as if the illegal or invalid provisions had not been included, and the illegal or invalid action shall be null and void.

- 10.12 <u>Governing Documents</u>. In the event of any contradiction between the Plan and any Award Agreement or any other written agreement between a Participant and the Company or any Subsidiary of the Company that has been approved by the Administrator, the terms of the Plan shall govern, unless it is expressly specified in such Award Agreement or other written document that a specific provision of the Plan shall not apply.
- 10.13 <u>Submission to Jurisdiction; Waiver of Jury Trial.</u> By accepting an Award, each Participant irrevocably and unconditionally consents to submit to the exclusive jurisdiction of the courts of the State of California and of the United States of America, in each case located in the State of California, for any action arising out of or relating to the Plan (and agrees not to commence any litigation relating thereto except in such courts), and further agrees that service of any process, summons, notice or document by U.S. registered mail to the address contained in the records of the Company shall be effective service of process for any litigation brought against it in any such court. By accepting an Award, each Participant irrevocably and unconditionally waives any objection to the laying of venue of any litigation arising out of Plan or Award hereunder in the courts of the State of California or the United States of America, in each case located in the State of California, and further irrevocably and unconditionally waives and agrees not to plead or claim in any such court that any such litigation brought in any such court has been brought in an inconvenient forum. By accepting an Award, each Participant irrevocably and unconditionally waives, to the fullest extent permitted by applicable law, any and all rights to trial by jury in connection with any litigation arising out of or relating to the Plan or any Award hereunder.
- 10.14 <u>Governing Law.</u> The provisions of the Plan and all Awards made hereunder shall be governed by and interpreted in accordance with the laws of the State of Delaware, disregarding choice-of-law principles of the law of any state that would require the application of the laws of a jurisdiction other than such state.
- Awards shall be subject to such terms and conditions as the Administrator shall determine, including, without limitation, restrictions on the transferability of shares of Common Stock, the right of the Company to repurchase shares of Common Stock, the right of the Company to require that shares of Common Stock be transferred in the event of certain transactions, tag-along rights, bring-along rights, redemption and co-sale rights and voting requirements. Such terms and conditions may be additional to those contained in the Plan and may, as determined by the Administrator, be contained in the applicable Award Agreement or in an exercise notice, stockholders' agreement or in such other agreement as the Administrator shall determine, in each case in a form determined by the Administrator. The issuance of such shares of Common Stock shall be conditioned on the Participant's consent to such terms and conditions and the Participant's entering into such agreement or agreements. All Awards (including any proceeds, gains or other economic benefit actually or constructively received by Participant upon any receipt or exercise of any Award or upon the receipt or resale of any shares of Common Stock underlying the Award) shall be subject to the provisions of any claw-back policy implemented by the Company, including, without limitation, any claw-back policy adopted to comply with the requirements of the Dodd-Frank Wall Street Reform and Consumer Protection Act and any rules or regulations promulgated thereunder, to the extent set forth in such claw-back policy and/or in the applicable Award Agreement.

- 10.16 <u>Titles and Headings</u>. The titles and headings of the Sections in the Plan are for convenience of reference only and, in the event of any conflict, the text of the Plan, rather than such titles or headings, shall control.
- 10.17 <u>Conformity to Securities Laws</u>. Participant acknowledges that the Plan is intended to conform to the extent necessary with all provisions of the Securities Act and the Exchange Act and any and all regulations and rules promulgated by the Securities and Exchange Commission thereunder, and state securities laws and regulations. Notwithstanding anything herein to the contrary, the Plan and all Awards granted hereunder shall be administered only in such a manner as to conform to such laws, rules and regulations. To the extent permitted by Applicable Laws, the Plan and all Award Agreements shall be deemed amended to the extent necessary to conform to such laws, rules and regulations.
  - 11. <u>Definitions</u>. As used in the Plan, the following words and phrases shall have the following meanings:
- 11.1 "<u>Administrator</u>" means the Board or a Committee to the extent that the Board's powers or authority under the Plan have been delegated to such Committee.
- 11.2 "<u>Applicable Laws</u>" means the requirements relating to the administration of equity incentive plans under U.S. federal and state securities, tax and other applicable laws, rules and regulations, the applicable rules of any stock exchange or quotation system on which the Common Stock is listed or quoted and the applicable laws and rules of any foreign country or other jurisdiction where Awards are granted or issued under the Plan.
- 11.3 "<u>Award</u>" means, individually or collectively, a grant under the Plan of Options, Restricted Stock, Restricted Stock Units or Other Stock-Based Awards.
- 11.4 "<u>Award Agreement</u>" means a written agreement evidencing an Award, which agreements may be in electronic medium and shall contain such terms and conditions with respect to an Award as the Administrator shall determine, consistent with and subject to the terms and conditions of the Plan.
  - 11.5 "Board" means the Board of Directors of the Company.
- 11.6 "Change in Control" means (i) a merger or consolidation of the Company with or into any other corporation or other entity or person, (ii) a sale, lease, exchange or other transfer in one transaction or a series of related transactions of all or substantially all of the Company's assets, or (iii) any other transaction, including the sale by the Company of new shares of its capital stock or a transfer of existing shares of capital stock of the Company, the result of which is that a third party that is not an affiliate of the Company or its stockholders (or a group of third parties not affiliated with the Company or its stockholders) immediately prior to such transaction acquires or holds capital stock of the Company representing a majority of the Company's outstanding voting power immediately following such transaction; provided that the following events shall not constitute a "Change in Control": (A) a transaction (other than a sale of all or substantially all of the Company's assets) in which the holders of the voting securities of the Company immediately prior to the merger or consolidation hold, directly or indirectly, at least a majority of the voting securities in the successor corporation or its parent immediately after the

merger or consolidation; (B) a sale, lease, exchange or other transaction in one transaction or a series of related transactions of all or substantially all of the Company's assets to an affiliate of the Company; (C) an initial public offering of any of the Company's securities; (D) a reincorporation of the Company solely to change its jurisdiction; or (E) a transaction undertaken for the primary purpose of creating a holding company that will be owned in substantially the same proportion by the persons who held the Company's securities immediately before such transaction. Notwithstanding the foregoing, if a Change in Control would give rise to a payment or settlement event with respect to any Award that constitutes "nonqualified deferred compensation," the transaction or event constituting the Change in Control must also constitute a "change in control event" (as defined in Treasury Regulation §1.409A-3(i)(5)) in order to give rise to the payment or settlement event for such Award, to the extent required by Section 409A.

- 11.7 "Code" means the Internal Revenue Code of 1986, as amended, and the regulations issued thereunder.
- 11.8 "<u>Committee</u>" means one or more committees or subcommittees of the Board, which may be comprised of one or more directors and/or executive officers of the Company, in either case, to the extent permitted in accordance with Applicable Laws.
  - 11.9 "Common Stock" means the common stock of the Company.
- 11.10 "Company" means Sana Biotechnology, Inc., a Delaware corporation, or any successor thereto. Except where the context otherwise requires, the term "Company" includes any of the Company's present or future parent or subsidiary corporations as defined in Sections 424(e) or (f) of the Code and any other business venture (including, without limitation, joint venture or limited liability company) in which the Company has a significant interest, as determined by the Administrator.
- 11.11 "Consultant" means any person, including any advisor, engaged by the Company or a parent or subsidiary of the Company to render services to such entity if: (i) the consultant or adviser renders *bona fide* services to the Company; (ii) the services rendered by the consultant or advisor are not in connection with the offer or sale of securities in a capital-raising transaction and do not directly or indirectly promote or maintain a market for the Company's securities; and (iii) the consultant or advisor is a natural person, or such other advisor or consultant as is approved by the Administrator.
- 11.12 "<u>Designated Beneficiary</u>" means the beneficiary or beneficiaries designated, in a manner determined by the Administrator, by a Participant to receive amounts due or exercise rights of the Participant in the event of the Participant's death or incapacity. In the absence of an effective designation by a Participant, "Designated Beneficiary" shall mean the Participant's estate.
  - 11.13 "<u>Director</u>" means a member of the Board.
- 11.14 "<u>Disability</u>" means a permanent and total disability within the meaning of Section 22(e)(3) of the Code, as it may be amended from time to time.

- 11.15 "<u>Dividend Equivalents</u>" means a right granted to a Participant pursuant to Section 6.4(c) hereof to receive the equivalent value (in cash or shares of Common Stock) of dividends paid on shares of Common Stock.
- 11.16 "<u>Employee</u>" means any person, including officers and Directors, employed by the Company (within the meaning of Section 3401(c) of the Code) or any parent or subsidiary of the Company.
- 11.17 "<u>Equity Restructuring</u>" means, as determined by the Administrator, a non-reciprocal transaction between the Company and its stockholders, such as a stock dividend, stock split, spin-off or recapitalization through a large, nonrecurring cash dividend, that affects the shares of Common Stock (or other securities of the Company) or the share price of Common Stock (or other securities of the Company) and causes a change in the per share value of the Common Stock underlying outstanding Awards.
  - 11.18 "Exchange Act" means the Securities Exchange Act of 1934, as amended.
- 11.19 "Fair Market Value" means, as of any date, the value of Stock determined as follows: (i) if the Common Stock is listed on any established stock exchange, its Fair Market Value shall be the closing sales price for such Common Stock as quoted on such exchange for such date, or if no sale occurred on such date, the first market trading day immediately prior to such date during which a sale occurred, as reported in *The Wall Street Journal* or such other source as the Administrator deems reliable; (ii) if the Common Stock is not traded on a stock exchange but is quoted on a national market or other quotation system, the last sales price on such date, or if no sales occurred on such date, then on the date immediately prior to such date on which sales prices are reported, as reported in *The Wall Street Journal* or such other source as the Administrator deems reliable; or (iii) in the absence of an established market for the Common Stock, the Fair Market Value thereof shall be determined by the Administrator in its sole discretion.
- 11.20 "<u>Incentive Stock Option</u>" means an "incentive stock option" as defined in Section 422 of the Code.
- 11.21 "<u>Non-Qualified Stock Option</u>" means an Option that is not intended to be or otherwise does not qualify as an Incentive Stock Option.
  - 11.22 "Option" means an option to purchase Common Stock.
- 11.23 "Other Stock-Based Awards" means other Awards of shares of Common Stock, and other Awards that are valued in whole or in part by reference to, or are otherwise based on, shares of Common Stock or other property.
  - 11.24 "Participant" means a Service Provider who has been granted an Award under the Plan.
  - 11.25 "Plan" means this 2018 Equity Incentive Plan.
- 11.26 "<u>Publicly Listed Company</u>" means that the Company or its successor (i) is required to file periodic reports pursuant to Section 12 of the Exchange Act and (ii) the Common

Stock is listed on one or more National Securities Exchanges (within the meaning of the Exchange Act) or is quoted on NASDAQ or a successor quotation system.

- 11.27 "<u>Restricted Stock</u>" means Common Stock awarded to a Participant pursuant to Section 6 hereof that is subject to certain vesting conditions and other restrictions.
- 11.28 "<u>Restricted Stock Unit</u>" means an unfunded, unsecured right to receive, on the applicable settlement date, one share of Common Stock or an amount in cash or other consideration determined by the Administrator equal to the value thereof as of such payment date, which right may be subject to certain vesting conditions and other restrictions.
- 11.29 "Section 409A" means Section 409A of the Code and all regulations, guidance, compliance programs and other interpretative authority thereunder.
  - 11.30 "Securities Act" means the Securities Act of 1933, as amended from time to time.
  - 11.31 "Service Provider" means an Employee, Consultant or Director.
  - 11.32 "<u>Termination of Service</u>" means the date the Participant ceases to be a Service Provider.

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#### SANA BIOTECHNOLOGY, INC.

#### 2018 EQUITY INCENTIVE PLAN

#### **CALIFORNIA SUPPLEMENT**

This supplement is intended to satisfy the requirements of Section 25102(o) of the California Corporations Code and the regulations issued thereunder ("Section 25102(o)"). Notwithstanding anything to the contrary contained in the Plan and except as otherwise determined by the Administrator, the provisions set forth in this supplement shall apply to all Awards granted under the Plan to a Participant who is a resident of the State of California on the date of grant (a "California Participant") and which are intended to be exempt from registration in California pursuant to Section 25102(o), and otherwise to the extent required to comply with applicable law (but only to such extent). Definitions in the Plan are applicable to this supplement.

- 1. <u>Limitation On Securities Issuable Under Plan</u>. The amount of securities issued pursuant to the Plan shall not exceed the amounts permitted under Section 260.140.45 of the California code of regulations to the extent applicable.
- 2. <u>Additional Limitations For Grants</u>. The terms of all Awards shall comply, to the extent applicable, with Sections 260.140.41 and 260.140.42 of the California Code of Regulations.
- 3. Additional Requirement To Provide Information To California Participants. The Company shall provide to each California Participant, not less frequently than annually, copies of annual financial statements (which need not be audited). The Company shall not be required to provide such statements to key persons whose duties in connection with the Company assure their access to equivalent information. In addition, this information requirement shall not apply to any plan or agreement that complies with all conditions of Rule 701 of the Securities Act ("Rule 701"); provided that for purposes of determining such compliance, any registered domestic partner shall be considered a "family member" as that term is defined in Rule 701.

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## SANA BIOTECHNOLOGY, INC.

## 2018 EQUITY INCENTIVE PLAN

## **AMENDMENT**

Pursuant to the authority reserved to the Board of Directors (the "**Board**") of Sana Biotechnologies, Inc., a Delaware corporation (the "**Company**"), under Section 10.4 of the Company's 2018 Equity Incentive Plan (the "**Plan**"), the Board hereby amends the Plan as follows.

1. The first sentence of Section 4.1 of the Plan is hereby amended to read in its entirety as follows:

"Subject to adjustment under Section 8 hereof, Awards may be made under the Plan covering up to 41,204,749 shares of Common Stock."

2. Except as set forth herein, the Plan shall remain in full force and effect in accordance with its terms.

\* \* \* \* \* \* \* \* \*

I hereby certify that the foregoing Amendment to the Plan was duly adopted by the Board effective as of January 30, 2020.

I hereby further certify that the foregoing Amendment to the Plan was duly adopted by the Company's stockholders effective as of February 20, 2020.

Executed on this 21st day of February, 2020.

/s/ James MacDonald

James MacDonald, Secretary

#### 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(f)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 8, 2021	Ву:	/s/ Steven D. Harr, M.D.	
		Steven D. Harr, M.D.	_
		President and Chief Executive Officer	
		(Principal Executive Officer)	

#### 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: November 8, 2021	By:	/s/ Nathan Hardy	
		Nathan Hardy	
		<b>Executive Vice President and Chief Financial Officer</b>	
		(Principal Financial and Accounting Officer)	

(Principal Executive Officer)

# 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 September 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: November 8, 2021	By:	/s/ Steven D. Harr, M.D.	
	· · · · · · · · · · · · · · · · · · ·	Steven D. Harr, M.D.  Procident and Chief Executive Officer	

# 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 September 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1)	The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
(2)	The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: November 8, 2021

Nathan Hardy
Executive Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

By: /s/ Nathan Hardy