

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549**

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended September 30, 2022

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-39941

**Sana Biotechnology, Inc.**

(Exact Name of Registrant as Specified in its Charter)

**Delaware**  
(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 telephone number, including area code: (206) 701-7914**

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share	SANA	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
Emerging growth company	<input checked="" type="checkbox"/>		

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

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

As of October 27, 2022, the registrant had 190,726,445 shares of common stock, \$0.0001 par value per share, outstanding.

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## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- our expectations regarding the potential market size and size of the potential patient populations for our product candidates and any future product candidates, if approved for commercial use;
  - our clinical and regulatory development plans;
  - our expectations with regard to the results of our preclinical studies, future clinical trials, and research and development programs, including the timing and availability of data from such studies and trials;
  - the timing of commencement of future preclinical studies, clinical trials, and research and development programs;
  - our ability to acquire, discover, and develop product candidates and advance them into, and successfully complete, clinical trials;
  - our intentions with respect to and our ability to establish collaborations or partnerships;
  - the timing or likelihood of regulatory filings and approvals for our product candidates;
  - our commercialization, marketing, and manufacturing expectations, including with respect to the buildout of our manufacturing facility and capabilities and the timing thereof;
  - impact of 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 ongoing COVID-19 pandemic, on our preclinical and clinical programs and business;
  - our expectations regarding the impact of the ongoing 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, needs for additional financing, and ability to obtain additional capital;
  - our expected use of 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 Jumpstart Our Business Startups Act of 2012 (JOBS Act); and
  - developments and projections relating to our competitors and our industry, including competing products.
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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 Quarterly 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 in a timely manner or 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 Quarterly 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. 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.

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**PART I. FINANCIAL INFORMATION****Item 1. Financial Statements**

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

	<u>September 30, 2022</u>	<u>December 31, 2021</u>
	(unaudited)	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 163,343	\$ 253,029
Marketable securities	322,407	297,967
Restricted cash	6,100	-
Prepaid expenses and other current assets	8,400	7,105
Total current assets	500,250	558,101
Long-term marketable securities	25,823	195,881
Property and equipment, net	67,349	65,464
Operating lease right-of-use assets	95,733	96,320
Long-term restricted cash	4,408	8,819
Intangible asset	59,195	59,195
Goodwill	140,627	140,627
Other non-current assets	4,717	5,000
<b>TOTAL ASSETS</b>	<b>\$ 898,102</b>	<b>\$ 1,129,407</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 3,993	\$ 2,219
Accrued compensation	24,500	21,131
Accrued expenses and other current liabilities	14,970	10,344
Operating lease liabilities	11,921	9,159
Contingent consideration	59,429	51,382
Success payment liabilities	-	5,000
Total current liabilities	114,813	99,235
Operating lease liabilities, net of current portion	99,859	101,784
Contingent consideration, net of current portion	81,701	102,361
Success payment liabilities, net of current portion	35,710	97,525
Total liabilities	332,083	400,905
<i>Commitments and contingencies (Note 9)</i>		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 50,000 shares authorized; zero shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	-	-
Common stock, \$0.0001 par value; 750,000 shares authorized; 189,885 and 184,929 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	19	18
Additional paid-in capital	1,546,807	1,515,210
Accumulated other comprehensive loss	(6,414)	(1,366)
Accumulated deficit	(974,393)	(785,360)
Total stockholders' equity	566,019	728,502
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 898,102</b>	<b>\$ 1,129,407</b>

*See accompanying notes.*

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Operating expenses:				
Research and development	\$ 76,735	\$ 53,245	\$ 221,964	\$ 140,121
Research and development related success payments and contingent consideration	(6,062)	16,753	(79,428)	67,778
General and administrative	15,514	13,433	48,240	37,731
Total operating expenses	<u>86,187</u>	<u>83,431</u>	<u>190,776</u>	<u>245,630</u>
Loss from operations	(86,187)	(83,431)	(190,776)	(245,630)
Interest income, net	1,173	158	2,149	409
Other income (expense), net	(106)	10	(406)	24
Net loss	<u>\$ (85,120)</u>	<u>\$ (83,263)</u>	<u>\$ (189,033)</u>	<u>\$ (245,197)</u>
Net loss per common share - basic and diluted	<u>\$ (0.45)</u>	<u>\$ (0.46)</u>	<u>\$ (1.01)</u>	<u>\$ (1.53)</u>
Weighted-average number of common shares - basic and diluted	<u>189,303</u>	<u>181,827</u>	<u>187,645</u>	<u>160,515</u>

*See accompanying notes.*

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Net loss	\$ (85,120)	\$ (83,263)	\$ (189,033)	\$ (245,197)
Other comprehensive loss, net of tax:				
Unrealized loss on marketable securities, net	(67)	(95)	(5,048)	(112)
Total comprehensive loss	<u>\$ (85,187)</u>	<u>\$ (83,358)</u>	<u>\$ (194,081)</u>	<u>\$ (245,309)</u>

*See accompanying notes.*

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

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance as of December 31, 2021	-	\$ -	184,929	\$ 18	\$ 1,515,210	\$ (1,366)	\$ (785,360)	\$ 728,502
Vesting of restricted stock	-	-	1,419	1	(1)	-	-	-
Exercise of stock options	-	-	284	-	652	-	-	652
Stock-based compensation expense	-	-	-	-	7,755	-	-	7,755
Unrealized loss on marketable securities, net	-	-	-	-	-	(3,806)	-	(3,806)
Net loss	-	-	-	-	-	-	(31,448)	(31,448)
Balance as of March 31, 2022	-	\$ -	186,632	\$ 19	\$ 1,523,616	\$ (5,172)	\$ (816,808)	\$ 701,655
Vesting of restricted stock	-	-	1,243	-	-	-	-	-
Exercise of stock options	-	-	320	-	571	-	-	571
Issuance of common stock related to employee stock purchase plan	-	-	235	-	1,008	-	-	1,008
Stock-based compensation expense	-	-	-	-	9,911	-	-	9,911
Unrealized loss on marketable securities, net	-	-	-	-	-	(1,175)	-	(1,175)
Net loss	-	-	-	-	-	-	(72,465)	(72,465)
Balance as of June 30, 2022	-	\$ -	188,430	\$ 19	\$ 1,535,106	\$ (6,347)	\$ (889,273)	\$ 639,505
Issuance of common stock from at the market offering, net of issuance costs of \$540	-	-	149	-	724	-	-	724
Vesting of restricted stock	-	-	927	-	-	-	-	-
Exercise of stock options	-	-	379	-	897	-	-	897
Stock-based compensation expense	-	-	-	-	10,080	-	-	10,080
Unrealized loss on marketable securities, net	-	-	-	-	-	(67)	-	(67)
Net loss	-	-	-	-	-	-	(85,120)	(85,120)
Balance as of September 30, 2022	-	\$ -	189,885	\$ 19	\$ 1,546,807	\$ (6,414)	\$ (974,393)	\$ 566,019

  

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance as of December 31, 2020	134,113	\$ 852,897	16,170	\$ 2	\$ 8,216	\$ 30	\$ (429,432)	\$ (421,184)
Conversion of convertible preferred stock into common stock upon initial public offering	(134,113)	(852,897)	134,113	13	852,884	-	-	852,897
Issuance of common stock in initial public offering, net of \$49,220 in offering costs	-	-	27,025	3	626,402	-	-	626,405
Vesting of restricted stock	-	-	1,428	-	-	-	-	-
Exercise of stock options	-	-	205	-	298	-	-	298
Stock-based compensation expense	-	-	-	-	4,158	-	-	4,158
Unrealized gain on marketable securities, net	-	-	-	-	-	26	-	26
Net loss	-	-	-	-	-	-	(180,617)	(180,617)
Balance as of March 31, 2021	-	\$ -	178,941	\$ 18	\$ 1,491,958	\$ 56	\$ (610,049)	\$ 881,983
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 securities, net	-	-	-	-	-	(43)	-	(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

See accompanying notes.



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

	<b>Nine Months Ended September 30,</b>	
	<b>2022</b>	<b>2021</b>
<b>OPERATING ACTIVITIES:</b>		
Net loss	\$ (189,033)	\$ (245,197)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	11,430	7,735
Stock-based compensation expense	27,746	15,049
Change in the estimated fair value of contingent consideration	(12,613)	10,080
Change in the estimated fair value of success payment liabilities	(66,815)	57,698
Non-cash expense for operating lease right-of-use assets	8,859	4,597
Other non-cash items, net	(6,687)	(2,255)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	569	(2,985)
Operating lease right-of-use assets and liabilities	1,584	5,028
Accounts payable	2,144	1,397
Accrued expenses and other liabilities	8,833	7,898
Net cash used in operating activities	<u>(213,983)</u>	<u>(140,955)</u>
<b>INVESTING ACTIVITIES:</b>		
Purchases of marketable securities	(63,583)	(414,437)
Proceeds from maturities of marketable securities	201,991	266,960
Purchases of property and equipment	(16,274)	(24,660)
Net cash provided by (used in) investing activities	<u>122,134</u>	<u>(172,137)</u>
<b>FINANCING ACTIVITIES:</b>		
Proceeds from initial public offering, net of issuance costs	-	626,405
Proceeds from employee stock purchase plan and exercise of stock options, net	3,128	2,227
Proceeds from at the market offering of common stock, net of issuance costs	724	-
Net cash provided by financing activities	<u>3,852</u>	<u>628,632</u>
Net (decrease) increase in cash, cash equivalents, and restricted cash	(87,997)	315,540
Cash, cash equivalents, and restricted cash at beginning of period	261,848	126,949
Cash, cash equivalents, and restricted cash at end of period	<u>\$ 173,851</u>	<u>\$ 442,489</u>
<b>SUPPLEMENTAL CASH FLOW INFORMATION:</b>		
Operating lease right-of-use assets obtained in exchange for lease obligations	\$ 21,073	\$ 26,257
Purchases of property and equipment included in accounts payable and accrued liabilities	\$ 2,409	\$ 3,231
Cash received for amounts related to tenant improvement allowances	\$ 2,014	\$ 5,160
Remeasurement of operating lease right-of-use asset for lease modification	\$ (12,801)	\$ -

*See accompanying notes.*

**Sana Biotechnology, Inc.**  
**Notes to Condensed Consolidated Financial Statements**  
**(unaudited)**

## **1. Organization**

Sana Biotechnology, Inc. (the Company or 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, developing and executing the Company's business plan, establishing the Company's intellectual property portfolio, raising capital, and providing general and administrative support for these operations.

### ***Liquidity and capital resources***

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, those related 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 technologies, 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 with the proceeds from additional equity or debt financings or 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.

In August 2022, the Company entered a sales agreement with Cowen and Company, LLC (Cowen), acting as sales agent, pursuant to which it may offer and sell through Cowen shares of the Company's common stock having an aggregate offering price of up to \$150.0 million from time to time in a series of one or more at the market equity offerings (collectively, the ATM facility). As of September 30, 2022, the Company had raised approximately \$0.7 million in net proceeds under the ATM facility.

In February 2021, the Company successfully completed the initial public offering (IPO) of its common stock. In connection with the 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.

The Company has incurred operating losses each year since inception and expects such losses to continue for the foreseeable future. As of September 30, 2022, the Company had cash, cash equivalents, and marketable securities of \$511.6 million, and an accumulated deficit of \$974.4 million, which includes cumulative non-cash charges related to the revaluation of the success payment liabilities and contingent consideration of \$33.3 million and \$89.9 million, respectively.

## **2. Basis of presentation and significant accounting policies**

### ***Basis of presentation***

The accompanying condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States (GAAP) and include the accounts of the Company and its wholly-owned subsidiaries. Certain prior period amounts have been reclassified to conform to current period presentation.

The condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2021 filed with the Securities and Exchange Commission (SEC) on March 16, 2022 (2021 Annual Report).

### ***Significant accounting policies***

The significant accounting policies used in the preparation of these condensed consolidated financial statements as of September 30, 2022 and for the three and nine months ended September 30, 2022 and 2021 are consistent with those discussed in Note 2 in the 2021 Annual Report.

### ***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, operating lease right-of-use assets and liabilities, and the valuation of stock options.

### ***Recent accounting pronouncements***

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (FASB) or other standard setting bodies that the Company adopts as of the specified effective date. Unless otherwise discussed, the Company does not believe that the adoption of recently issued standards has had or may have a material impact on its condensed consolidated financial statements or disclosures.

## **3. Acquisitions**

### ***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.

As part of the Cobalt acquisition, the Company recorded an intangible asset of \$59.2 million, which consists of in-process research and development that is classified as indefinite-lived until the successful development of the associated research and development technology, at which point it becomes a finite-lived asset and will be amortized over its estimated useful life. If the research and development technology is abandoned, an impairment charge will be recorded. The Company is actively developing the fusogen technology and, accordingly, development of the intangible asset is not complete. Amortization will begin when regulatory approval of a product based on the fusogen technology is obtained in a major market, typically either the United States or the European Union.

The Company recognized \$140.6 million of goodwill as a result of the Cobalt acquisition, which is primarily attributable to the value the acquisition provides the Company by complementing the Company's *ex vivo* portfolio with the *in vivo* fusogen cell engineering technology and furthering the Company's research in using engineered cells as medicines. The goodwill is not deductible for income tax purposes. There were no impairments of the intangible asset or goodwill since the acquisition.

Pursuant to the terms and conditions in the Cobalt acquisition agreement, the Company has an obligation to pay certain former Cobalt stockholders up to an aggregate of \$500.0 million in contingent consideration (Cobalt Contingent Consideration) upon the achievement of certain pre-specified development milestones, and a success payment (Cobalt Success Payment) of up to \$500.0 million, payable in cash or stock. The Cobalt Success Payment is payable if, at pre-determined valuation measurement dates, which include the closing of 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, or has filed for, or received approval for, a biologics license application or new drug application. The Cobalt Success Payment can be achieved over a maximum of 20 years from the date of the acquisition, but this period could be shorter upon the occurrence of certain events. As of September 30, 2022, a Cobalt Success Payment had not been triggered.

A valuation measurement date would also 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:

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

The Cobalt Success Payment and Cobalt Contingent Consideration liabilities are carried at fair value, with changes in fair value recognized in the statements of operations in research and development related success payments and contingent consideration. As of September 30, 2022 and December 31, 2021, the estimated fair value of the Cobalt Success Payment liability was \$31.9 million and \$88.3 million, respectively, and was recorded in long-term liabilities in the balance sheets. In connection with the change in the estimated fair value of the Cobalt Success Payment, the Company recognized expenses of \$2.4 million and \$21.8 million for the three months ended September 30, 2022 and 2021, respectively, and a gain of \$56.5 million and expense of \$46.9 million, for the nine months ended September 30, 2022 and 2021, respectively.

As of September 30, 2022, the estimated fair value of the Cobalt Contingent Consideration was \$141.1 million, of which \$59.4 million was recorded in short-term liabilities and \$81.7 million was recorded in long-term liabilities in the balance sheet. As of December 31, 2021, the estimated fair value of the Cobalt Contingent Consideration was \$153.7 million, of which \$51.4 million was recorded in short-term liabilities and \$102.3 million was recorded in long-term liabilities in the balance sheet. In connection with the change in the estimated fair value of the Cobalt Contingent Consideration, the Company recognized gains of \$8.3 million and \$8.5 million for the three months ended September 30, 2022 and 2021, respectively, and a gain of \$12.6 million and an expense of \$10.1 million for the nine months ended September 30, 2022 and 2021, respectively.

#### **4. License and collaboration agreements**

##### ***Beam Therapeutics Inc.***

In October 2021, the Company entered into an option and license agreement (Beam Agreement) with Beam Therapeutics Inc. (Beam), pursuant to which the Company was granted 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. The Company made an upfront cash payment of \$50.0 million to Beam, which was recorded in research and development expense for the year ended December 31, 2021. Additionally, under the terms of the agreement, the Company may be obligated to pay 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 was, at the time of entry into the Beam Agreement, a beneficial owner of Beam, and is affiliated with a member of the board of directors of Beam.

##### ***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 hypimmune cells.

Under the terms of the agreement, the Company may be required to pay to Harvard up to an aggregate of \$175.0 million in success payments, 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 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 the Company's Series A convertible preferred stockholders, and the last day of the term of the Harvard Success Payments. As of September 30, 2022, a Harvard Success Payment had not been triggered.

The aggregate amount of the Harvard Success Payments will not exceed an aggregate of \$175.0 million, which payment amount would only occur upon a 40x increase in the fair value of the Company's common stock 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. 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 can be achieved over a maximum of 12 years from the effective date of the agreement.

The following table summarizes the potential success payments and common stock price required for payment:

<b>Multiple of Equity Value at Issuance</b>	<b>5x</b>	<b>10x</b>	<b>20x</b>	<b>30x</b>	<b>40x</b>
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 in the statements of operations in research and development related success payments and contingent consideration. As of September 30, 2022, the estimated fair value of the Harvard Success Payment liability was \$3.8 million, which was recorded in long-term liabilities in the balance sheet. As of December 31, 2021, the estimated fair value of the Harvard Success Payment liability was \$14.2 million, of which \$5.0 million was recorded in short-term liabilities and \$9.2 million was recorded in long-term liabilities in the balance sheet. In connection with the change in the estimated fair value of the Harvard Success Payment liability, the Company recognized a gain of \$0.2 million and an expense of \$3.4 million, respectively, for the three months ended September 30, 2022 and 2021, and a gain of \$10.3 million and an expense of \$10.8 million, respectively, for the nine months ended September 30, 2022 and 2021.

## 5. Restricted cash

As of September 30, 2022 and December 31, 2021, the Company maintained standby letters of credit of \$10.5 million and \$8.8 million, respectively, which are collateralized with a bank account at a financial institution in accordance with the applicable lease agreements. The Company's letter of credit related to its lease for industrial space located in Fremont, California will reduce from \$6.7 million to \$0.6 million in July 2023, and as such, \$6.1 million in restricted cash is included in current assets on the balance sheet as of September 30, 2022.

## 6. 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:

	Valuation Hierarchy	September 30, 2022			Estimated Fair Value
		Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	
(in thousands)					
Financial assets:					
Cash equivalents:					
Money market funds	Level 1	\$ 74,981	\$ -	\$ -	\$ 74,981
U.S. government and agency securities	Level 2	54,644	7	(2)	54,649
Corporate debt securities	Level 2	200	-	-	200
Total cash equivalents		<u>129,825</u>	<u>7</u>	<u>(2)</u>	<u>129,830</u>
Short-term marketable securities:					
U.S. government and agency securities	Level 2	278,844	5	(4,859)	273,990
Corporate debt securities	Level 2	49,096	-	(679)	48,417
Total short-term marketable securities		<u>327,940</u>	<u>5</u>	<u>(5,538)</u>	<u>322,407</u>
Long-term marketable securities:					
U.S. government and agency securities	Level 2	26,709	-	(886)	25,823
Total long-term marketable securities		<u>26,709</u>	<u>-</u>	<u>(886)</u>	<u>25,823</u>
Other assets	Level 3	370	-	-	370
Total financial assets		<u>\$ 484,844</u>	<u>\$ 12</u>	<u>\$ (6,426)</u>	<u>\$ 478,430</u>
Financial liabilities:					
Short-term financial liabilities:					
Contingent consideration	Level 3	\$ 59,429	\$ -	\$ -	\$ 59,429
Total short-term financial liabilities		<u>59,429</u>	<u>-</u>	<u>-</u>	<u>59,429</u>
Long-term financial liabilities:					
Contingent consideration	Level 3	81,701	-	-	81,701
Success payment liabilities	Level 3	35,710	-	-	35,710
Total long-term financial liabilities		<u>117,411</u>	<u>-</u>	<u>-</u>	<u>117,411</u>
Total financial liabilities		<u>\$ 176,840</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 176,840</u>

	Valuation Hierarchy	December 31, 2021			
		Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Estimated Fair Value
(in thousands)					
<b>Financial assets:</b>					
Cash equivalents:					
Money market funds	Level 1	\$ 224,671	\$ -	\$ -	\$ 224,671
Corporate debt securities	Level 2	2,345	-	-	2,345
<b>Total cash equivalents</b>		<b>227,016</b>	<b>-</b>	<b>-</b>	<b>227,016</b>
Short-term marketable securities:					
U.S. government and agency securities	Level 2	162,854	1	(195)	162,660
Corporate debt securities	Level 2	135,441	-	(134)	135,307
<b>Total short-term marketable securities</b>		<b>298,295</b>	<b>1</b>	<b>(329)</b>	<b>297,967</b>
Long-term marketable securities:					
U.S. government and agency securities	Level 2	176,492	-	(925)	175,567
Corporate debt securities	Level 2	20,427	-	(113)	20,314
<b>Total long-term marketable securities</b>		<b>196,919</b>	<b>-</b>	<b>(1,038)</b>	<b>195,881</b>
Other assets	Level 3	426	-	-	426
<b>Total financial assets</b>		<b>\$ 722,656</b>	<b>\$ 1</b>	<b>\$ (1,367)</b>	<b>\$ 721,290</b>
<b>Financial liabilities:</b>					
Short-term financial liabilities:					
Contingent consideration	Level 3	\$ 51,382	\$ -	\$ -	\$ 51,382
Success payment liabilities	Level 3	5,000	-	-	5,000
<b>Total short-term financial liabilities</b>		<b>56,382</b>	<b>-</b>	<b>-</b>	<b>56,382</b>
Long-term financial liabilities:					
Contingent consideration	Level 3	102,361	-	-	102,361
Success payment liabilities	Level 3	97,525	-	-	97,525
<b>Total long-term financial liabilities</b>		<b>199,886</b>	<b>-</b>	<b>-</b>	<b>199,886</b>
<b>Total financial liabilities</b>		<b>\$ 256,268</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ 256,268</b>

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 and 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.

The following table summarizes available-for-sale debt securities in a continuous unrealized loss position for less than and greater than twelve months, for the periods presented:

	Less than 12 months		12 months or greater		Total	
	Fair value	Unrealized losses	Fair value	Unrealized losses	Fair value	Unrealized losses
(in thousands)						
<b>September 30, 2022</b>						
U.S. government and agency securities	\$ 110,150	\$ (1,425)	\$ 193,970	\$ (4,322)	\$ 304,120	\$ (5,747)
Corporate debt securities	14,000	(272)	34,617	(407)	48,617	(679)
<b>Total</b>	<b>\$ 124,150</b>	<b>\$ (1,697)</b>	<b>\$ 228,587</b>	<b>\$ (4,729)</b>	<b>\$ 352,737</b>	<b>\$ (6,426)</b>
<b>December 31, 2021</b>						
U.S. government and agency securities	\$ 329,883	\$ (1,120)	\$ -	\$ -	\$ 329,883	\$ (1,120)
Corporate debt securities	156,662	(247)	-	-	156,662	(247)
<b>Total</b>	<b>\$ 486,545</b>	<b>\$ (1,367)</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ 486,545</b>	<b>\$ (1,367)</b>

As of September 30, 2022 and December 31, 2021, the fair value of securities held by the Company in an unrealized loss position were \$352.7 million and \$486.5 million, respectively. As of September 30, 2022, there were 34 securities held by the

Company in an unrealized loss position that had been in an unrealized loss position over 12 months, and no securities in an unrealized loss position over 12 months as of December 31, 2021. The Company determined that there was no material change in the credit risk of the investments described above during the three and nine months ended September 30, 2022. As such, an allowance for credit losses has not been recognized. As of September 30, 2022, 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, 2022, 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, 2022, the balance in accumulated other comprehensive loss included the net unrealized losses related to the Company's available-for-sale debt securities. There were no material realized gains or losses recognized on the maturity of available-for-sale securities during the three and nine months ended September 30, 2022 or 2021.

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, 2021	\$ 153,743	\$ 88,353	\$ 14,172
Changes in fair value - gain	(528)	(46,823)	(8,087)
Balance as of March 31, 2022	153,215	41,530	6,085
Changes in fair value - gain	(3,830)	(12,073)	(2,025)
Balance as of June 30, 2022	149,385	29,457	4,060
Changes in fair value - expense (gain)	(8,255)	2,439	(246)
Balance as of September 30, 2022	<u>\$ 141,130</u>	<u>\$ 31,896</u>	<u>\$ 3,814</u>

### 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 ongoing basis as additional data impacting the assumptions are obtained.

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

Unobservable Input	September 30, 2022		December 31, 2021	
	Range	Weighted-Average	Range	Weighted-Average
Discount rates	18.0% - 20.7%	19.2%	10.9% - 11.6%	11.2%
Probability of milestone achievement	3.3% - 85.0%	34.5%	5.0% - 75.0%	33.8%

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 each 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: 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:

Unobservable Input	September 30, 2022		December 31, 2021	
	Cobalt	Harvard	Cobalt	Harvard
Expected stock price volatility	70%	70%	70%	70%
Expected term (years)	16.4	8.5	17.1	9.2

## 7. Property and equipment, net

Property and equipment, net consists of the following:

	September 30, 2022	December 31, 2021
	(in thousands)	
Laboratory equipment	\$ 59,511	\$ 47,684
Leasehold improvements	34,427	33,848
Construction in progress	835	1,388
Computer equipment, software, and other	2,772	1,318
Total property and equipment, at cost	97,545	84,238
Less: Accumulated depreciation	(30,196)	(18,774)
Property and equipment, net	\$ 67,349	\$ 65,464

Depreciation expense was \$4.0 million and \$2.8 million for the three months ended September 30, 2022 and 2021, respectively, and \$11.4 million and \$7.7 million for the nine months ended September 30, 2022 and 2021, respectively.

## 8. Accrued liabilities

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

	September 30, 2022	December 31, 2021
	(in thousands)	
Accrued compensation:		
Accrued bonuses	\$ 13,575	\$ 13,814
Accrued paid time off	5,550	4,429
Accrued payroll	5,375	2,888
Total accrued compensation	\$ 24,500	\$ 21,131
Accrued expenses and other current liabilities:		
Accrued research and development services	\$ 8,610	\$ 3,419
Accrued professional fees	2,317	1,971
Accrued property and equipment	1,795	2,566
Other accrued current liabilities	2,248	2,388
Total accrued expenses and other current liabilities	\$ 14,970	\$ 10,344

## 9. Commitments and contingencies

### Lease commitments

The Company's lease portfolio primarily comprises operating leases for office, laboratory, non-good manufacturing practices (GMP) pilot plant manufacturing, and industrial space. 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. Certain leases include options to extend the term. The renewal option is considered in the remaining lease term for the lease only when the Company is reasonably certain it will renew the lease. 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.

In June 2022, the Company entered into a lease agreement for 79,565 square feet of office, laboratory, and industrial space located in Bothell, Washington (the Bothell facility). The initial term of the lease is 16 years from the date the premises are delivered to the Company for construction of certain tenant improvements and includes the option to extend the lease for up to three additional five-year terms. The lease agreement also provides for up to \$19.9 million for reimbursement of tenant improvements, as well as an

additional \$8.0 million for tenant improvements, available at the Company's election, which the Company would be obligated to repay to the landlord monthly over the initial term of the lease with interest at a rate of 6.5% per annum. The Company will be obligated to pay base rent of approximately \$68.8 million over the initial term of the lease. In accordance with the lease agreement, the Company has obtained a letter of credit in the amount of \$1.6 million. The Company plans to recognize the right-of-use asset and lease liability when the lease commences.

In July 2021, the Company entered into a lease for industrial space located in Fremont, California (the Fremont facility), with the intent to establish and develop its manufacturing operations at the Fremont facility. However, the Company determined in June 2022 to establish and develop its manufacturing operations at the Bothell facility rather than the Fremont facility. The original right-of-use asset and lease liability for the Fremont facility was calculated assuming the Company would exercise its option to renew the lease for two additional five-year terms. The Company remeasured the lease for the Fremont facility due to the shorter expected lease term, which resulted in a \$12.8 million reduction in the related right-of-use asset and lease liability. Additionally, for the nine months ended September 30, 2022, the Company wrote-off \$4.5 million of construction in progress costs incurred in connection with the Fremont facility in general and administrative expense in the statement of operations.

The following table contains additional information related to the Company's operating leases:

Location	Use	Approximate Square Footage	Commencement Dates	Expiration Dates
Seattle, WA	Office/Laboratory	48,000	March 2019 to September 2020	December 2026 to April 2028
Cambridge, MA	Office/Laboratory	60,000	March 2019 to May 2020	November 2025 to February 2028
South San Francisco, CA	Office/Laboratory	100,000	December 2019 to April 2022	April 2024 to April 2030
Fremont, CA	Industrial	163,000	July 2021	November 2031
Rochester, NY	Office/Laboratory	3,000	January 2022	January 2025
Bothell, WA	Office/Laboratory/Industrial	80,000	January 2023	December 2038

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

The following table summarizes the Company's lease costs:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
	(in thousands)			
Operating lease cost	\$ 6,146	\$ 4,303	\$ 17,692	\$ 11,368
Short-term lease cost	-	-	-	512
Variable lease cost	1,831	1,286	5,223	4,015
Total lease cost	\$ 7,977	\$ 5,589	\$ 22,915	\$ 15,895

As of September 30, 2022, the weighted-average remaining lease term was 6.4 years, and the weighted-average incremental borrowing rate was 9.65%.

The following table reconciles the Company's undiscounted operating lease cash flows by fiscal year, as of September 30, 2022 (in thousands):

2022 (remaining 3 months)	\$ 4,733
2023	25,113
2024	24,326
2025	24,302
2026	21,183
2027 and thereafter	55,103
Total undiscounted lease payments	154,760
Less: imputed interest	(41,663)
Less: tenant improvement allowances	(1,317)
Present value of operating lease liabilities	111,780
Less: current portion of operating lease liabilities	(11,921)
Operating lease liabilities, net of current portion	\$ 99,859

## 10. Stockholders' equity

The Company amended and restated its certificate of incorporation, effective February 2021, which increased 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, 2022, there were 189.9 million shares of the Company's common stock outstanding, excluding 0.8 million shares of restricted common stock outstanding that were subject to vesting requirements.

In August 2022, the Company put in place the ATM facility, under which the Company entered a sales agreement with Cowen, acting as sales agent, pursuant to which the Company may offer and sell through Cowen shares of the Company's common stock having an aggregate offering price of up to \$150.0 million from time to time in a series of one or more at the market equity offerings. As of September 30, 2022, the Company had raised approximately \$0.7 million in net proceeds under the ATM facility.

## 11. Stock-based compensation

### Equity incentive plans

In February 2021, the Company adopted the 2021 Incentive Award Plan (2021 Plan) and the 2021 Employee Stock Purchase Plan (2021 ESPP), both of which became effective on the completion of the Company's IPO. The 2021 Plan provides for a variety of stock-based compensation awards, including stock options, restricted stock awards (RSAs), and restricted stock units (RSUs). 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 may 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 period or on the purchase date. As of September 30, 2022, 12.6 million shares and 3.6 million shares were available for future issuance under the 2021 Plan and the 2021 ESPP, respectively.

### Stock-based compensation expense

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
	(in thousands)			
Research and development	\$ 7,437	\$ 4,072	\$ 20,557	\$ 9,888
General and administrative	2,643	1,878	7,189	5,161
Total stock-based compensation expense	<u>\$ 10,080</u>	<u>\$ 5,950</u>	<u>\$ 27,746</u>	<u>\$ 15,049</u>

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, 2022 are as follows:

	Stock Options	RSAs	RSUs
Unrecognized stock-based compensation expense (in thousands)	\$ 92,582	\$ 860	\$ 5,317
Weighted-average period costs expected to be recognized (in years)	2.8	1.0	2.5

## 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 (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2021	17,337	\$ 8.96	8.7	\$ 141,718
Granted	11,375	6.15		
Exercised	(983)	2.16		
Forfeited/Cancelled	(2,187)	8.53		
Outstanding as of September 30, 2022	25,542	\$ 8.00	8.6	\$ 24,279
Exercisable as of September 30, 2022	6,604	\$ 6.90	7.8	\$ 13,114

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:

Assumptions	Nine Months Ended September 30,	
	2022	2021
Risk free interest rate	1.56% - 3.94%	0.46% - 1.15%
Expected volatility	70%	70%
Expected term (years)	5.50 - 6.25	5.50 - 6.40
Expected dividend	0%	0%

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

	Nine Months Ended September 30,	
	2022	2021
Weighted average grant date fair value per share for options granted	\$ 3.96	\$ 14.64
Aggregate intrinsic value of stock options exercised (in thousands)	\$ 5,854	\$ 22,187

## Restricted stock

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

	RSAs (in thousands)	RSAs Weighted-Average Grant Date Fair Value per Share	RSUs (in thousands)	RSUs Weighted-Average Grant Date Fair Value per Share
Unvested shares as of December 31, 2021	4,365	\$ 0.43	141	\$ 9.43
Granted	-	-	983	6.33
Vested	(3,530)	0.28	(59)	8.56
Forfeited	(29)	-	(88)	4.66
Unvested shares as of September 30, 2022	806	\$ 1.13	977	\$ 6.82

The fair value of RSAs vested during the nine months ended September 30, 2022 and 2021 was \$1.0 million and \$1.1 million, respectively. The fair value of RSUs vested during the nine months ended September 30, 2022 and 2021 was \$0.4 million and \$0.3 million, respectively.

## 12. 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.

The Company applies judgment in its determination of the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. As of September 30, 2022 and December 31, 2021, the Company's uncertain tax positions were immaterial.

### 13. 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 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 securities were excluded from the calculation of net loss per diluted share of common stock for periods presented as their effect would have been anti-dilutive:

	Nine Months Ended September 30,	
	2022	2021
	(in thousands)	
Options to purchase common stock	25,542	17,284
Unvested restricted common stock	806	5,791
Unvested RSUs	977	150
Total	<u>27,325</u>	<u>23,225</u>

## 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 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 Annual Report on Form 10-K as filed with the SEC on March 16, 2022 (2021 Annual Report). This discussion and analysis and other parts of this Quarterly Report contain forward-looking statements that are 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 numerous 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 *ex vivo* and *in 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. Our platform progress, broad capabilities, and strong balance sheet enable us to execute on a broad vision, with a goal of submitting our first investigational new drug application (IND) in 2022, with the opportunity to file multiple INDs per year beyond 2022.

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 islet 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 allogeneic, fully-differentiated cells sourced from a donor as the starting material to which we then apply our hypoimmune genetic modifications.

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. There are multiple methods available to modify the genome, but limited ability to deliver therapeutic payloads *in vivo*. Thus, delivery of a therapeutic payload is 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.

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 *ex vivo* and *in 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 (CELL TYPES)	THERAPEUTIC AREA	PRODUCT CANDIDATE	POTENTIAL INDICATIONS	PRE-CLINICAL	PHASE		
							1	2	3
Ex vivo cell engineering	Hypoimmune donor-derived	T cells	Oncology	SC291 [CD19]	NHL/ALL/CLL				
				SC276 [CD22 (+CD19)]	NHL/ALL/CLL				
				SC255 [BCMA]	Multiple myeloma				
	Hypoimmune stem cell-derived	Islet cells	Diabetes	SC451	Type 1 diabetes				
					Huntington's disease				
	Stem cell-derived (to migrate to hypoimmune)	Glial progenitor cells	Central nervous system (CNS)	SC379	Pelizaeus-Merzbacher disease				
Secondary progressive multiple sclerosis									
	Cardiomyocytes	Cardiovascular	SC187	Heart failure					
In vivo cell engineering	Fusogen	T cells	Oncology	SG295 [CD8/CD19]	NHL/ALL/CLL				
				SG239 [CD8/BCMA]	Multiple myeloma				
				SG242 [CD4/CD19]	NHL/ALL/CLL				
				SG221 [CD4/BCMA]	Multiple myeloma				
				SG233 [CD8/CD22 (+CD19)]	NHL/ALL/CLL				
		Hematopoietic stem cells	Hemoglobinopathies	SG418	Sickle cell disease				
					Beta-thalassemia				

We continue to make progress on developing our cell engineering platforms and advancing our product candidates through preclinical development and toward potential IND submissions. Given the depth and breadth of our portfolio, we expect to continue 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 toward potential IND submissions, we are conducting GLP toxicity studies and establishing necessary scale-up for our manufacturing processes.

We remain on track to file an IND in 2022 for our hypoimmune-modified CD19-targeted allogeneic CAR T (SC291). Preclinical data continue to highlight the potential for our hypoimmune platform to hide our allogeneic cells from immune detection, creating the potential for longer CAR T cell persistence and higher durable complete response rates in cancer patients. Our *in vivo* CAR T with CD8-targeted fusogen delivery of a CD19-targeted CAR (SG295) has the potential to generate CAR T cells *in vivo*, which would potentially eliminate the need for conditioning chemotherapy and complex CAR T cell manufacturing. We have demonstrated the ability to safely and selectively deliver the CAR gene to T cells *in vivo* and to generate active CAR T cells in multiple preclinical models. Recently, our scientists have made progress in a second-generation manufacturing process that results in at least a 50X improvement in product potency, which we believe has the potential to translate into better efficacy, safety and long-term manufacturability. In the fourth quarter of 2022, we decided to bring this second-generation process forward for our first-in-human studies in patients with B cell malignancies. While implementing this change in our manufacturing process will delay the IND for our SG295 program until 2023, we believe the improved process has the potential to provide a better therapy for patients.

Our goal is to also file an IND for our *ex vivo* hypoimmune allogeneic CD19/CD22 CAR T (SC276) product candidate as early as 2023 and an IND for our *ex vivo* hypoimmune islet cell (SC451) product candidate as early as 2024. The SC276 program will incorporate our hypoimmune platform, potentially offering greater persistence compared to other allogeneic CAR T therapies, and target CD22 and/or CD19 expressing cells. This therapy has the potential to treat patients with B cell malignancies who have either failed previous CAR T therapies or are naive to CAR T therapy. The SC451 program also leverages our hypoimmune platform. The goal of SC451 is to transplant hypoimmune islet cells with no immunosuppression into patients with type 1 diabetes so that these cells produce insulin in a physiologic manner in response to glucose. We believe each of these programs has the potential to generate clinical data in 2024. Based on our current timelines for our lead programs, we believe our cash runway will enable multiple data readouts across our platforms. For details regarding our product candidates, see the section titled “Business— Overview” in Part I, Item 1 included in our 2021 Annual Report.

Our *ex vivo* and *in vivo* technologies represent an aggregation of years of innovation and technology from multiple academic institutions and companies, including 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, fusogen technology acquired

from Cobalt Biomedicines Inc. (Cobalt), and genome editing technology licensed from Beam Therapeutics Inc. (Beam), among others. For details regarding these acquisitions and license and collaboration agreements, see Note 3, Acquisitions and Note 4, License and collaboration agreements, to our consolidated financial statements included in our 2021 Annual Report, as well as the section titled “Business— Key Intellectual Property Agreements” in Part I, Item 1 included in our 2021 Annual Report.

We were incorporated in July 2018, and our operations to date have included developing our *ex vivo* and *in vivo* cell engineering platforms, identifying and developing potential product candidates, executing preclinical studies, establishing manufacturing capabilities, acquiring technology, organizing and staffing the company, developing and executing our business plan, 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, 2022 and 2021 were \$189.0 million and \$245.2 million, respectively, and resulted primarily from our research and development programs, and, to a lesser extent, general and administrative costs associated with our operations. As of September 30, 2022, we had an accumulated deficit of \$974.4 million, which includes non-cash charges of \$33.3 million and \$89.9 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 \$25.00 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, 2022, we had cash, cash equivalents, and marketable securities of \$511.6 million. Based on our current operating plan, we believe that our existing cash, cash equivalents, and marketable securities will be sufficient to meet our working capital and capital expenditure needs for at least the next 12 months.

We anticipate that our expenses and operating losses will increase for 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 *ex vivo* and *in 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 capabilities, including developing our contract development and manufacturing relationships and building our internal manufacturing capabilities; acquire and license technologies aligned with our *ex vivo* and *in 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, prosecute, and defend our intellectual property portfolio; and incur additional legal, accounting, or other expenses in operating our business, including the costs associated with operating as a public company.

We are investing early in building world class capabilities in key areas of manufacturing sciences and operations, including development of our *ex vivo* and *in 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 our 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 we can generate significant product revenue, if ever, we expect to finance our operations with our existing cash, cash equivalents, and marketable securities, the proceeds of 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 continue to monitor it closely. The extent of the impact of the ongoing COVID-19 pandemic on our business, operations, and clinical development timelines and plans remains uncertain and will depend on certain developments, including the duration of the COVID-19 pandemic and spread of COVID-19, and the pandemic’s impact on our ability to build out and operationalize our internal manufacturing facility, expand our laboratory space, and enroll patients in clinical trials, and the impact of the pandemic on our clinical trial sites, contract research organizations (CROs), contract development and manufacturing organizations (CDMOs), 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 stay-at-home orders in



Washington, California, and Massachusetts, where our operations are located. However, to the extent possible, we are conducting business as usual, with many of our administrative employees continuing to work outside of our offices on at least a part-time basis.

### **Acquisitions**

We have completed various acquisitions since inception. For details regarding our acquisitions, see the section titled “Business—Key Intellectual Property Agreements” and Note 3, Acquisitions, to our consolidated financial statements included in our 2021 Annual Report.

### **License and collaboration agreements**

We have entered into license and collaboration agreements with various third parties. For details regarding these agreements, see the section titled “Business—Key Intellectual Property Agreements” and Note 4, License and collaboration agreements, to our consolidated financial statements included in our 2021 Annual Report.

### **Success payments and contingent consideration**

#### *Cobalt success payment and contingent consideration*

Pursuant to the terms and conditions of the Cobalt acquisition agreement, we are obligated to pay to certain former Cobalt stockholders contingent consideration (Cobalt Contingent Consideration) of up to an aggregate of \$500.0 million upon our achievement of certain pre-specified development milestones and a success payment (Cobalt Success Payment) of up to \$500.0 million, each of which is payable in cash or stock. The Cobalt Success Payment is payable if, at pre-determined valuation measurement dates, which include the closing of 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 or new drug application. A valuation measurement date would also 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 such change of control, the amount of the potential Cobalt Success Payment will decrease, and the amount of potential Cobalt Contingent Consideration will increase. As of September 30, 2022, a Cobalt Success Payment had not been triggered.

See Note 3, Acquisitions to our condensed consolidated financial statements included elsewhere in this Quarterly Report for details on the amount of the potential Cobalt Success Payment and potential Cobalt Contingent Consideration if there is a change of control based on various thresholds for our market capitalization on such change of control date. 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 2021 Annual Report 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 up to an aggregate of \$175.0 million in success payments to Harvard (Harvard Success Payments), payable in cash, based on increases in the per share fair market 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 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. Future valuation measurement dates are triggered by certain events, which include the one-year anniversary of our IPO, and periodically thereafter, the date of the consummation of a merger, an asset sale, the sale of the majority of the shares held by our Series A convertible preferred stockholders, and the last day of the term of the Harvard 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 Harvard Success Payments made are credited against the Harvard 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, 2022, a Harvard Success Payment had not been triggered.

See Note 4, License and collaboration agreements to our condensed consolidated financial statements included elsewhere in this Quarterly Report for details on the various per share common stock values that trigger a Harvard Success Payment. 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 2021 Annual Report 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, including CDMO manufacturing costs (including pass-through costs) and clinical trial costs, costs for laboratory supplies, costs to acquire and license technologies aligned with our goal of translating engineered cells to medicines, facility 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 reliably estimated 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 *ex vivo* and *in vivo* cell engineering platforms, identifying and developing product candidates, and establishing manufacturing capabilities. Due to our early stage of development, the number of ongoing projects, and our ability to use resources across several projects, the 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 for the foreseeable future as we expand our research and development efforts, including by expanding the capabilities of our cell engineering platforms, identifying product candidates, completing existing preclinical studies and commencing new preclinical studies, 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 Success Payment and Harvard Success Payment liabilities and Cobalt Contingent Consideration liability. The expense or gain associated with our research and development related success payments and contingent consideration is unpredictable, in part, because our success payments are impacted by changes in our common stock price and market capitalization at the end of each reporting period, and may continue to 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, legal, executive, human resources, and information technology 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. Included in general and administrative expenses for the nine months ended September 30, 2022 are construction in progress costs incurred in connection with the write-off of our previously planned manufacturing facility in Fremont, California (Fremont facility), which will be replaced by our facility in Bothell, Washington (Bothell facility).

We anticipate that our general and administrative expenses will increase over the foreseeable future to support our expanded research and development activities, grow our business, and support future possible business development opportunities, but at a slower rate than our research and development expenses. We also anticipate that we will continue 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, director and officer insurance costs, investor relations activities, and other administrative and professional services.

## Results of operations

### Comparison of the three and nine months ended September 30, 2022 and 2021

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2022	2021	Change	2022	2021	Change
	(in thousands)					
Operating expenses:						
Research and development	\$ 76,735	\$ 53,245	\$ 23,490	\$ 221,964	\$ 140,121	\$ 81,843
Research and development related success payments and contingent consideration	(6,062)	16,753	(22,815)	(79,428)	67,778	(147,206)
General and administrative	15,514	13,433	2,081	48,240	37,731	10,509
Total operating expenses	<u>86,187</u>	<u>83,431</u>	<u>2,756</u>	<u>190,776</u>	<u>245,630</u>	<u>(54,854)</u>
Loss from operations	(86,187)	(83,431)	(2,756)	(190,776)	(245,630)	54,854
Interest income, net	1,173	158	1,015	2,149	409	1,740
Other income (expense), net	(106)	10	(116)	(406)	24	(430)
Net loss	<u>\$ (85,120)</u>	<u>\$ (83,263)</u>	<u>\$ (1,857)</u>	<u>\$ (189,033)</u>	<u>\$ (245,197)</u>	<u>\$ 56,164</u>

#### 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,		Change
	2022	2021	
	(in thousands)		
Personnel	\$ 30,950	\$ 20,972	\$ 9,978
Research, development, and laboratory	20,080	13,326	6,754
Third-party manufacturing	7,845	4,612	3,233
Facility and other allocated costs	16,286	13,199	3,087
Other	1,574	1,136	438
Total research and development expense	<u>\$ 76,735</u>	<u>\$ 53,245</u>	<u>\$ 23,490</u>

Research and development expense was \$76.7 million and \$53.2 million for the three months ended September 30, 2022 and 2021, respectively. The increase of \$23.5 million was primarily due to:

- an increase of \$10.0 million in personnel-related expenses, including an increase in non-cash stock-based compensation of \$3.4 million, which was attributable to an increase in headcount to expand our research and development capabilities;
- an increase of \$6.8 million in research, development, and laboratory costs;
- an increase of \$3.2 million in third-party manufacturing costs for CDMOs, including pass-through costs for materials; and
- an increase of \$3.1 million in facility costs, including rent and depreciation, and allocated overhead costs.

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

	Nine Months Ended September 30,		Change
	2022	2021	
	(in thousands)		
Personnel	\$ 89,077	\$ 56,105	\$ 32,972
Research, development, and laboratory	54,314	39,188	15,126
Third-party manufacturing	20,941	6,848	14,093
Facility and other allocated costs	47,441	33,667	13,774
Acquisition and licensing of technology	6,602	1,845	4,757
Other	3,589	2,468	1,121
Total research and development expense	<u>\$ 221,964</u>	<u>\$ 140,121</u>	<u>\$ 81,843</u>

Research and development expense was \$222.0 million and \$140.1 million for the nine months ended September 30, 2022 and 2021, respectively. The increase of \$81.9 million was primarily due to:

- an increase of \$33.0 million in personnel-related expenses, including an increase in non-cash stock-based compensation of \$10.7 million, which was attributable to an increase in headcount to expand our research and development capabilities;
- an increase of \$15.1 million in research, development, and laboratory costs;
- an increase of \$14.1 million in third-party manufacturing costs for CDMOs, including pass-through costs for materials;
- an increase of \$13.8 million in facility costs, including rent and depreciation, and allocated overhead costs; and
- an increase of \$4.8 million primarily related to licensing technology related to our CD22 and BCMA programs.

*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 for the periods presented:

	<u>Three Months Ended September 30,</u>		
	2022	2021	Change
	(in thousands)		
Cobalt success payment	\$ 2,439	\$ 21,790	\$ (19,351)
Harvard success payments	(246)	3,439	(3,685)
Contingent consideration	(8,255)	(8,476)	221
Total research and development related success payments and contingent consideration	<u>\$ (6,062)</u>	<u>\$ 16,753</u>	<u>\$ (22,815)</u>

The expense related to the change in the estimated fair value of our Cobalt Success Payment was \$2.4 million for the three months ended September 30, 2022, compared to \$21.8 million for the same period in 2021. The changes in value were due to changes in our market capitalization and scientific progress toward filing an IND for SG295 during the relevant periods. The gain related to the change in the estimated fair value of our Harvard Success Payments was \$0.2 million for the three months ended September 30, 2022, compared to an expense of \$3.4 million for the same period in 2021. The changes in value were due to changes in our common stock price during the relevant periods. The gain related to the change in the estimated fair value of our Cobalt Contingent Consideration was \$8.3 million for the three months ended September 30, 2022, compared to \$8.5 million for the same period in 2021. The changes in value were primarily due to variability of the discount rates used in the calculation offset by scientific progress toward the achievement of milestones during the relevant periods.

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

	<u>Nine Months Ended September 30,</u>		
	2022	2021	Change
	(in thousands)		
Cobalt success payment	\$ (56,457)	\$ 46,915	\$ (103,372)
Harvard success payments	(10,358)	10,783	(21,141)
Contingent consideration	(12,613)	10,080	(22,693)
Total research and development related success payments and contingent consideration	<u>\$ (79,428)</u>	<u>\$ 67,778</u>	<u>\$ (147,206)</u>

The gain related to the change in the estimated fair value of our Cobalt Success Payment was \$56.5 million for the nine months ended September 30, 2022, compared to an expense of \$46.9 million for the same period in 2021. The changes in value were due to changes in our market capitalization and scientific progress toward filing an IND for SG295 during the relevant periods. The gain related to the change in the estimated fair value of our Harvard Success Payments was \$10.4 million for the nine months ended September 30, 2022, compared to an expense of \$10.8 million for the same period in 2021. The changes in value were due to changes in our common stock price during the relevant periods. The gain related to the change in the estimated fair value of our Cobalt Contingent Consideration was \$12.6 million for the nine months ended September 30, 2022, compared to an expense of \$10.1 million for the same period in 2021. The changes in value were primarily due to variability of the discount rates used in the calculation offset by scientific progress toward the achievement of milestones during the relevant periods.

### *General and administrative Expenses*

General and administrative expenses were \$15.5 million and \$48.2 million for the three and nine months ended September 30, 2022, respectively, compared to \$13.4 million and \$37.7 million for the same periods in 2021, respectively.

The increase of \$2.1 million for the three months ended September 30, 2022 was primarily due to operating costs related to the Fremont facility of \$1.0 million and non-cash stock-based compensation of \$0.8 million.

The increase of \$10.5 million for the nine months ended September 30, 2022 was primarily due to increased personnel-related expenses of \$4.6 million, including non-cash stock-based compensation of \$2.1 million, primarily attributable to an increase in headcount to build our infrastructure, the write-off of \$4.5 million of construction in progress costs incurred in connection with the Fremont facility, and operating costs related to the Fremont facility of \$1.1 million. These increases were partially offset by a decrease in legal fees of \$1.6 million.

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

#### ***Sources of liquidity***

As of September 30, 2022, we had \$511.6 million in cash, cash equivalents, and marketable securities. To date we have raised an aggregate of approximately \$1.3 billion in net proceeds from sales of common stock and private placements of our convertible preferred stock.

In August 2022, we entered into a sales agreement with Cowen and Company, LLC (Cowen), acting as sales agent, pursuant to which we may offer and sell shares of our common stock having an aggregate offering price of up to \$150.0 million from time to time in a series of one or more at the market equity offerings (collectively, the ATM facility). As of September 30, 2022, we had raised approximately \$0.7 million in net proceeds under the ATM facility.

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

Based on our current operating plan, we believe that our existing cash, cash equivalents, and marketable securities will be sufficient to meet our working capital and capital expenditure needs for at least the next 12 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 or future product candidates;
- the number and scope of clinical trials required for regulatory approval of our current or future product candidates;
- the costs, timing, and outcome of regulatory review of our current or future product candidates;
- the cost, timing, and scope of 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;
- the expenses required to attract, hire, and retain skilled personnel;
- the impact of global supply chain issues and rising rates of inflation on the costs of laboratory consumables, supplies, and equipment required for our ongoing operations;
- 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 payors;
- potential interruptions or delays resulting from factors related to the ongoing 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 proceeds of equity or debt financings or 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 debt, 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 or 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,	
	2022	2021
	(in thousands)	
Net cash provided by (used in):		
Operating activities	\$ (213,983)	\$ (140,955)
Investing activities	122,134	(172,137)
Financing activities	3,852	628,632
Net increase (decrease) in cash, cash equivalents, and restricted cash	<u>\$ (87,997)</u>	<u>\$ 315,540</u>

#### Operating activities

During the nine months ended September 30, 2022, net cash used in operating activities was \$214.0 million, consisting primarily of net loss of \$189.0 million, the change in net operating assets and liabilities of \$13.1 million, and non-cash adjustments of \$38.1 million. The non-cash adjustments of \$38.1 million consisted of gains of \$66.8 million and \$12.6 million for revaluation of our success payment liabilities and contingent consideration, respectively, non-cash stock-based compensation expense of \$27.7 million, depreciation expense of \$11.4 million, and other non-cash adjustments of \$2.2 million.

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

### Investing activities

During the nine months ended September 30, 2022, cash provided by investing activities was \$122.1 million, consisting of net purchases and maturities of marketable securities of \$138.4 million, partially offset by purchases of property and equipment of \$16.3 million. During the nine months ended September 30, 2021, cash used in investing activities was \$172.1 million, consisting of net purchases and maturities of marketable securities of \$147.4 million, and purchases of property and equipment of \$24.7 million.

### Financing activities

During the nine months ended September 30, 2022, cash provided by financing activities was \$3.9 million, consisting primarily of proceeds from issuance of common stock. 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.

### Contractual obligations and commitments

The following table summarizes our significant contractual obligations and commitments as of September 30, 2022:

	Payments Due by Period				Total
	Less than 1 Year	1 to 3 Years	3 to 5 Years (in thousands)	More than 5 Years	
Operating lease obligations <sup>(1)</sup>	\$ 22,742	\$ 54,713	\$ 49,972	\$ 96,144	\$ 223,571

- (1) As part of our decision to move the site of our manufacturing facility to Bothell, Washington from Fremont, California, we intend to sublease or terminate the lease for the Fremont facility.

Other than as disclosed in the table above, the payment obligations under our license, collaboration, and acquisition agreements as of September 30, 2022 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 2021 Annual Report 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, pursuant to the terms and conditions in the Cobalt acquisition agreement, and up to an aggregate of \$175.0 million in success payments to Harvard, 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 2021 Annual Report and Note 4, License and collaboration agreements, to our condensed consolidated financial statements located elsewhere in this Quarterly Report for more information on these success payments. As of September 30, 2022, 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 remain an emerging growth company until the earliest to occur of (1) December 31, 2026, (2) the last day of the fiscal year in which we have total annual gross revenue of at least \$1.235 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, 2022, and for the three and nine months ended September 30, 2022 and 2021 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 2021 Annual Report.

### **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, 2022, we had cash, cash equivalents, and restricted cash of \$173.9 million, which consisted of bank deposits and money market funds. We also had marketable securities of \$348.2 million as of September 30, 2022. 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, 2022.

#### **Market capitalization and common stock price sensitivity**

We agreed to make a success payment to Cobalt, payable in cash or stock, based on our market capitalization, and success payments to Harvard, payable in cash, based on increases in the per share fair market value of our common stock. As of September 30, 2022, the estimated fair value of the Cobalt and Harvard success payment liabilities was \$35.7 million. For the three and nine months ended September 30, 2022, we recorded an expense of \$2.2 million and a gain of \$66.8 million, respectively, related to the aggregate change in the estimated fair value of our success payment liabilities. Changes in our market capitalization and the fair value of our common stock as of each balance sheet date may have a relatively large change in the estimated fair value of the success payment liabilities and resulting expense or gain. See Item 1A. Risk Factors included in this Quarterly Report for a sensitivity analysis showing the impact that a hypothetical change in our market capitalization and common stock value would have had on our results for the year ended September 30, 2022.

#### **Foreign Currency**

We are not currently exposed to significant market risk related to changes in foreign currency exchange rates; however, we do contract with vendors that are located outside of the United States and may be subject to fluctuations in foreign currency rates. We may enter into additional contracts with vendors located outside of the United States in the future, which may increase our foreign currency exchange risk.

#### **Effects of Inflation**

Inflation generally affects us by increasing our cost of labor and laboratory consumables. 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, 2022, management, including 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 our Chief Executive Officer and 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, 2022, 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, 2022 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 in the ordinary course of business face various claims brought by third parties, and we may make claims or take legal action 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 multiple 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 successful or not, 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, including our financial statements and related notes included elsewhere in this Quarterly Report, before making an investment decision. The risks described below are not the only ones we face. 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 ongoing COVID-19 pandemic and any worsening of the global geo-political, business, and economic environment. 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 a 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:

- Our *ex vivo* and *in vivo* cell engineering platforms are based on novel technologies that are unproven and may not result in approvable or marketable products. This uncertainty exposes us to unforeseen risks, makes it difficult for us to predict the time that will be required for the development and potential regulatory approval of our product candidates, and increases the risk that we may ultimately not be successful in our efforts to use and expand our technology platforms to build a pipeline of product candidates.
- 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.
- While we believe our pipeline will yield multiple investigational new drug applications (INDs), we may not be able to submit INDs to commence clinical trials on the timelines we expect, and even if we are able to submit INDs, the United States Food and Drug Administration (FDA) may not permit us to proceed with clinical trials.
- We may not realize the benefits of technologies that we have acquired, or will acquire in the future, or any collaborative or licensing arrangements or other strategic transactions that we have or will consummate. 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 ability to develop our cell engineering platforms and product candidates and our future growth depend on retaining our key personnel and recruiting additional qualified personnel.
- We may encounter difficulties in managing our growth as we continue to expand our development and regulatory capabilities, which could disrupt our operations.
- The use of human stem cells exposes us to a number of risks in the development of our human stem cell-derived products, including an inability to obtain suitable donor material from eligible and qualified human donors, restrictions on the use of human stem cells, as well as the ethical, legal, and social implications of research using stem cells, any of which could prevent us from completing the development of or commercializing and gaining acceptance for our products derived from human stem cells.

- 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 any of our product candidates are prolonged or delayed, we may be unable to obtain required regulatory approvals and commercialize such product candidates on a timely basis or at all.
- Our future clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of our product candidates, including any future product candidates, which would prevent, delay, or limit the scope of regulatory approval and commercialization of such product candidates.
- Our product candidates may have serious adverse, undesirable, or unacceptable side effects or other properties that may delay or prevent marketing approval. If a product candidate receives regulatory approval, and such side effects are identified following such approval, the commercial profile of any approved label may be limited, or we may be subject to other significant negative consequences following such approval.
- The manufacture of our product candidates is complex. We or our third-party contract development and manufacturing organizations (CDMOs) 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.
- We are exposed to a number of risks related to the supply chain for the materials required to manufacture our product candidates.
- We rely on, and expect to continue to rely on, third parties to perform certain activities, including research and preclinical studies, manufacture of our product candidates and materials used to manufacture our product candidates, including testing of such product candidates and materials, and the conduct of various aspects of our planned clinical trials. Any failure of such third parties to perform their obligations to us, including in accordance with our timelines or applicable regulatory requirements, could materially harm our business.
- Our success depends on our ability to protect our intellectual property rights and our proprietary technologies.
- We depend on intellectual property licensed from 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.
- Our internal computer systems, or those used by our third-party research institution collaborators, contract research organizations (CROs), CDMOs, or other contractors or consultants, may fail or suffer security breaches.
- 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 unable to obtain regulatory approval for our product candidates on a timely basis, or at all, our business will be substantially harmed.
- 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 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, drain our cash resources, or cause us to incur debt to satisfy the payment obligations.
- Our limited operating history may make it difficult to evaluate our prospects and likelihood of success.
- We or the third parties upon whom we depend may be adversely affected by natural disasters, public health epidemics, such as the ongoing COVID-19 pandemic, telecommunications or electrical failures, geo-political actions, including war and terrorism, political and economic instability, and other events beyond our control, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

## Risks Related to Our Business and Industry

***Our ex vivo and in vivo cell engineering platforms are based on novel technologies that are unproven and may not result in approvable or marketable products. This uncertainty exposes us to unforeseen risks, makes it difficult for us to predict the time and cost that will be required for the development and potential regulatory approval of our product candidates, and increases the risk that we may ultimately 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 *ex vivo* and *in 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 that utilize fusogen technology or that are cell products derived from pluripotent stem cells (PSCs). Further, the scientific evidence that supports 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.

Preclinical and clinical testing of product candidates is inherently unpredictable and may lead to unexpected results, in particular when such product candidates are based on novel technologies. For example, we have not tested our cell engineering platforms on all pluripotent and differentiated cell types or in all microenvironments, and results from one cell type or microenvironment may not translate into other cell types or microenvironments. In addition, our current gene editing approaches rely on novel gene editing reagents that may have unanticipated or undesirable effects or prove to be less effective than we expect. Also, we have not tested any of the product candidates that we are developing using our cell engineering platforms in humans. Further, our current data are limited to animal models and preclinical cell lines and assays, which may not accurately predict the safety and efficacy of our product candidates in humans. We may encounter significant challenges creating appropriate models and assays for evaluating the safety and purity of our product candidates and may not be able to provide sufficient data or other evidence, to the satisfaction of regulatory authorities, that certain unexpected results observed in preclinical and clinical testing of our product candidates are not indicative of the potential safety issues of such product candidates.

In addition, our hypoimmune and fusogen technologies have potential safety risks, including those related 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. PSC-derived cell products may have potential safety risks related to genomic and epigenomic variations that have been observed during passage (i.e., amplification) and differentiation of pluripotent cell lines. We cannot always predict the types and potential impact of these genomic changes, including whether certain changes are or may eventually be harmful. Accordingly, it may be difficult for us to conduct the level of testing and development of assays necessary to ensure the safety of our PSC-derived cell product candidates in humans. These risks related to genetic variation are also relevant to our product candidates created from donor-derived cells. Additionally, our stem cell-based product candidates have potential safety risks that may result from cells that are undifferentiated or have not been completely differentiated to the desired phenotype and lead 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, as described elsewhere in these Risk Factors.

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 experience with similar therapeutics or delivery methods, the regulatory pathway with the FDA and comparable foreign regulatory authorities may be more complex, time-consuming, and unpredictable relative to more well-known therapeutics.

Moreover, even if we obtain human data to support continued evaluation and approval of our product candidates, the FDA or comparable foreign regulatory authorities may lack experience in evaluating the safety and efficacy of therapeutics similar to our product candidates. For example, given that there are no approved PSC- or donor-derived cell products on the market, the FDA and comparable foreign regulatory authorities have not established consistent standards by which to evaluate the safety of such products, and any such standards that they do establish may subsequently change. Moreover, the FDA remains focused on potential safety issues associated with gene and cell therapy products and has placed clinical holds on certain product candidates pending further evaluation of genomic abnormalities detected in as few as a single patient following administration of such product candidates. We cannot be certain that the FDA or comparable foreign regulatory authorities will determine that the potential safety risks associated with our product candidates outweigh the potential therapeutic benefits, and that they will allow us to commence clinical trials of such product candidates in a timely manner, or at all, or to continue such clinical trials once they have commenced. If we become subject to a clinical hold with respect to any of our product candidates due to a potential safety issue, we cannot guarantee that we will be able to provide the applicable regulatory authority with sufficient data or other evidence regarding the safety of such product candidate such that we can resume clinical development of such product candidates in a timely manner or at all. This could delay clinical

development of such product candidate or our other product candidates, increase our expected development costs, increase the length of the regulatory review process, and delay or prevent commercialization of our product candidates. Moreover, even if we and the applicable regulatory authorities determine that our product candidates are safe in humans, and such products obtain approval, they may later prove to cause serious adverse side effects in patients that we were unable to observe or predict during the clinical development of such product candidates, which may subject us to significant negative consequences, as described elsewhere in these Risk Factors. In addition, the evaluation process for our product candidates takes time and resources and may require independent third-party analyses, and our product candidates may not be accepted or approved by the FDA or comparable foreign regulatory authorities. We cannot be certain that our *ex vivo* and *in vivo* cell engineering platforms will lead to the development of approvable or marketable products, either alone or in combination with other therapies.

Additionally, a key element of our strategy is to use and expand our *ex vivo* and *in vivo* cell engineering platforms to build a pipeline of product candidates and advance those product candidates through clinical development for the treatment of a variety of different types of diseases. Even if we are successful in building our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including if they are shown to have harmful side effects or other characteristics that indicate that they are unlikely to receive marketing approval and achieve market acceptance. If we do not successfully develop, obtain approval for, and commercialize any of our current or future product candidates, we will face difficulty in generating or be unable to generate 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 to occur for at least the next several years, if ever, will depend heavily on the timely and successful identification, development, regulatory approval, and eventual commercialization of any such product candidates, which may never occur. To date, we have not generated revenue from sales of any products, and we may never be able to develop, obtain regulatory approval for, or commercialize a marketable product. All of our current product candidates are in preclinical development, and, before we generate any revenue from product sales, will require that we manage preclinical, clinical, and manufacturing activities, undertake significant clinical development, obtain regulatory approval in multiple jurisdictions, establish manufacturing supply, including commercial manufacturing supply, and build a commercial organization, which will require a substantial investment and significant marketing efforts. We may never receive regulatory approval for any of our product candidates, which would prevent us from marketing or promoting any of our product candidates.

The successful development of our product candidates will depend on or be affected by numerous factors, including the following:

- our successful and timely completion of preclinical studies and clinical trials for which the FDA and any comparable foreign regulatory authorities agree with the design, endpoints, and implementation;
- the sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- our receipt of regulatory approvals or authorizations to conduct future clinical trials;
- our ability to timely and successfully initiate, enroll patients in, and complete clinical trials;
- 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, has suitable purity, and is potent as a treatment 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;
- the timely receipt of marketing approvals for our product candidates from applicable regulatory authorities;
- our ability to address any potential interruptions or delays resulting from factors related to the ongoing COVID-19 pandemic;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities, including the conduct of any post-marketing approval clinical studies, and our ability to comply with any such commitments; and
- our ability to establish, scale up, and scale out, either alone or with third-party manufacturers, manufacturing capabilities for clinical supply of our product candidates for our clinical trials and, if any of our product candidates are approved, commercial supply (including licensure) of such product candidates.

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

If we experience issues with or delays with respect to any one or more of these factors, we could experience significant delays or be unable to successfully develop and commercialize our product candidates, which would materially adversely affect our business, financial condition, and results of operations.

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

We expect our pipeline to yield multiple INDs beginning as early as 2022. We cannot be sure that, following our submission of an IND, the FDA or comparable foreign regulatory authorities will allow our clinical trials to begin, or that, once begun, issues will not arise that require suspension or termination of such clinical trials. The manufacturing of our product candidates remains an emerging and evolving field. Accordingly, we expect topics relating to chemistry, manufacturing, and controls, including product specifications, will be a focus of IND reviews, which may delay the clearance of INDs that we submit. Additionally, even if applicable regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or comparable foreign submission, such regulatory authorities may change their requirements in the future, which could require us to make costly changes to and delay the conduct of our clinical trials or require suspension or termination of such trials entirely.

***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 consummated or will consummate.***

Our *ex vivo* and *in vivo* cell engineering technologies represent an aggregation of years of innovation and technology from multiple academic institutions and companies, including our fusogen technology that we acquired from Cobalt Biomedicine, Inc. (Cobalt), our *ex vivo* cell engineering programs focused on replacing damaged cells in the heart and certain brain disorders that we acquired from Cytocardia Inc. (Cytocardia) and Oscine Corp. (Oscine), respectively, hypimmune technology that we licensed from the President and Fellows of Harvard College (Harvard) and The Regents of the University of California (UCSF), and gene editing technology that we licensed from Beam Therapeutics Inc., among 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 level of success of these strategic transactions, including any future strategic transactions, will depend on the risks and uncertainties involved, including:

- unanticipated liabilities related to acquired companies or joint ventures;
- difficulty integrating acquired personnel, technologies, and operations into our existing business;
- difficulty retaining key employees, including of any acquired businesses;
- diversion of management time and focus from operating our business to management of acquisition and integration efforts, strategic alliances or collaborations, or joint venture challenges;
- increases in our expenses and reductions in our cash available for operations and other uses;
- higher than expected collaboration, acquisition, or integration costs;
- disruption in our relationships with collaborators, key suppliers, manufacturers, or customers as a result of such transactions;
- incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs;
- possible write-offs of assets, goodwill or impairment charges, or increased amortization expenses relating to acquired businesses or joint ventures;
- difficulty in and cost of facilitating the collaboration or combining the operations and personnel of any acquired business with our own; and
- challenges integrating acquired businesses into our business, including our existing operations and culture.

In addition, 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. The occurrence of any of these risks or uncertainties may preclude us from realizing the anticipated benefit of any acquisition or strategic transaction, and our financial condition may be harmed.

Additionally, we may not be successful in our efforts to acquire or obtain rights to certain technologies or products that are necessary for the success of our product candidates on acceptable terms or at all, including because we may be unable to successfully or timely negotiate the terms of an agreement with the third-party owner of such technology or products or because such third party may have determined to deprioritize such technology or products. If we are not able to acquire or obtain rights to certain technologies or products on which certain of our product candidates may depend, it may be necessary for us to curtail, reduce, or delay the development of such 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. In addition, our *ex vivo* and *in vivo* cell engineering platforms are attractive technologies for potential collaborations due to their breadth of application. Therefore, for certain of our product candidates, including product candidates that we may develop in the future, we may decide to form or seek strategic alliances, collaborations, or licensing arrangements with pharmaceutical or biotechnology companies that we believe will complement or augment our development and potential commercialization efforts with respect to such product candidates, including in territories outside the United States or for certain indications.

We face significant competition in seeking appropriate collaborators. Collaborations are complex and time-consuming to negotiate and document. We may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates on acceptable terms or at all, including because our product candidates may be deemed to be at too early of a stage of development for collaborative effort or third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. Additionally, there have been a significant number of recent business combinations among large pharmaceutical companies that have reduced the number of potential future collaborators and changed the strategies of the resulting combined companies. In addition, under the terms of certain license agreements applicable to our product candidates, we may be restricted from entering into agreements on certain terms or at all with potential collaborators relating to those product candidates. If and when we collaborate with a third party for development and commercialization of a product candidate, we expect that we may have 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 for collaboration and could determine that such other collaboration is more attractive than a collaboration with us for our product candidate.

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

- collaborators may have significant discretion in determining the efforts and resources that they will apply to a collaboration and may not commit sufficient efforts and resources to the product development or marketing programs or may misapply those efforts and resources;
- collaborators may experience financial difficulties;
- 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 clinical trials, fail to provide sufficient 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 to our product candidates, such as marketing, distribution, and intellectual property rights;
- we may be required to agree to exclusivity, non-competition, or other terms that restrict our ability to research, develop, or commercialize certain existing product candidates or potential future product candidates, including our ability to develop

our product candidates in certain indications or geographic regions or combine our product candidates with certain third-party products;

- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property rights or proprietary information or expose us to potential liability;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- collaborators may acquire outside of the collaboration or develop, independently or in collaboration with third parties, including our competitors, products that compete directly or indirectly with our products or product candidates and may move forward with such products instead of ours;
- collaborators may own or co-own intellectual property rights covering our products that result from our collaboration, and in such cases, we may not have an exclusive right to commercialize the product candidates covered by such intellectual property rights;
- we and our collaborators may disagree regarding the development plan for a product candidate with respect to which we are collaborating, including, for example, with respect to target indications, inclusion or exclusion criteria for a clinical trial, or the decision to seek approval as front-line therapy versus second-, third-, or fourth-line therapy;
- 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 may 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 our collaboration;
- collaborations may be terminated, which may require us to obtain additional capital to pursue further development or commercialization of the applicable product candidates; or
- we may not achieve the revenue or specific net income that justifies our having entered into a transaction or the other anticipated benefits that led us to enter into the arrangement.

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 of the 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 we are unable to enter into strategic collaborations, or if any of the other events described in this paragraph occur after we enter into a collaboration, 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.

***Our ability to develop our cell engineering platforms and product candidates and our future growth depend 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 and their underlying technologies and related product candidates. Given the specialized nature of our *ex vivo* and *in vivo* cell engineering and the fact that we are operating in novel and emerging fields, there is an inherent scarcity of personnel with the requisite experience to fill the roles across our organization. As we continue developing our product candidates and building our pipeline, we will require personnel with medical, scientific, or technical qualifications specific to each program. The loss of key management and senior scientists could delay our research and development activities. In addition, the loss of key executives could disrupt our operations and our ability to conduct our business. Despite our efforts to retain valuable employees, members of our management, scientific, and development teams may terminate their employment with us at any time, sometimes on short notice. Although we have employment agreements with certain of our key employees, all of our employees are at-will employees, which means that they could leave our employment at any time, with or without notice. If our retention efforts are unsuccessful now or 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 50% to his time to the University of Washington, and Dr. Fry currently devotes approximately 25% of his time to the University of Colorado. We may in the future have other employees that have similar employment arrangements. These arrangements expose us to the risk that these individuals 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 employees, including executives, scientists, engineers, clinical operations and manufacturing personnel, 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 may be able to provide prospective job candidates or our existing employees with more attractive roles, salaries, or benefits than we can provide. 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 or are otherwise viewed unfavorably compared to those of companies with which we compete for talent, our ability to recruit and retain highly skilled employees could be harmed. 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.

***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. We cannot guarantee 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 and manufacture a sufficient and compliant supply of our product candidates, our clinical trials and the commercial viability of our product candidates could be adversely affected.***

The manufacture of biopharmaceutical products is complex and requires significant expertise, including the development of advanced manufacturing techniques and process controls. Manufacturers of gene and cell therapy 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 include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, and shortages of qualified personnel, as well as compliance with strictly enforced federal, state, and foreign regulations. As a result of the complexities involved in biopharmaceutical manufacturing, the cost to manufacture biologics is generally higher than traditional small molecule chemical compounds and the manufacturing process is less reliable and is more difficult to reproduce, and this is particularly true with respect to our product candidates. 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 in a compliant and cost-effective manner or at all.

We are investing early in building world class capabilities in key areas of manufacturing sciences and operations, including development of our *ex vivo* and *in 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 that we use, or the technologies that we incorporate into these processes, will result in viable or scalable yields of *ex vivo* and *in vivo* cell engineering product candidates that will be safe and effective and meet market demand.

A key part of our strategy is operating our own manufacturing capabilities, including our own manufacturing facilities. In July 2021, we entered into a long-term lease to establish and operate our own current good manufacturing practices (cGMP) manufacturing facility in Fremont, California to support our late-stage clinical development and early commercial product candidates across our product portfolio, including with respect to the production of allogeneic CAR T cells, viral vectors, and PSC-derived products. In June 2022, we decided to move the site of our planned manufacturing facility from Fremont, California to a new facility located in Bothell, Washington and entered into a long-term lease to establish and develop our cGMP manufacturing facility in Bothell, Washington (the Bothell facility). We expect that it will take at least several years before we are able to begin manufacturing our product candidates at the Bothell facility, if we are able to do so at all. In addition, in January 2022, we entered into an agreement with the University of Rochester Medical Center (URMC), pursuant to which we have obtained access to manufacturing capabilities within URMC's cell-based manufacturing facility (the URMC site) to support manufacturing of product candidates across our portfolio for early-stage clinical trials.

Designing and building out our Bothell facility and the URMC site will be time-consuming and require significant resources, including a reallocation of certain of our existing financial, human, and other 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 capabilities may be more expensive than we expect. We do not have experience as a company in developing internal manufacturing capabilities, and we may experience unexpected costs or delays or be unsuccessful in developing our internal manufacturing capabilities in time to support registration-enabling clinical trials of our product candidates or at all. In order to build out the Bothell facility and the URMC site, we will need to engage third-party service providers and obtain equipment and third-party technology necessary to manufacture our product candidates. 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 the Bothell 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 the facility without further delay or cost.

In addition, operating our Bothell facility and the URMC site 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, this may be difficult given the intense competition for qualified personnel in the biotechnology and pharmaceutical industries. In addition, though we plan to design and build out our manufacturing capacities at the URMC site, we do not control URMC's cell-based manufacturing facility, nor do we have control over how URMC manages and operates this facility. If URMC does not maintain its cell-based manufacturing facility in accordance with our requirements, we may not be able to manufacture our product candidates in a timely manner or at all, which may delay our ability to commence clinical trials for, obtain regulatory approval for, and commercialize our product candidates.

Until we are able to begin manufacturing our product candidates internally, we will rely on CDMOs to manufacture our product candidates for preclinical studies and clinical trials. Moreover, given our decision to move the site of our planned manufacturing facility from the Fremont facility to the Bothell facility, it may take us longer to establish and operationalize our Bothell facility than we originally anticipated, which may delay our ability to begin manufacturing certain of our product candidates internally and extend the period of time during which we must rely on CDMOs for the manufacture of such product candidates. For example, we may rely on our CDMOs for the potential registration and commercial launch of our first product candidate under our current clinical development timelines, and if there are any delays in our ability to establish and operationalize the Bothell facility, we may be required to rely on our CDMOs for the potential registrations and commercial launches of additional product candidates as well.

Once we have completed the build-out of the Bothell facility and the URMC site, we may be required to transition manufacturing processes and know-how of certain of our product candidates to the Bothell facility and URMC site. To date, we and our CDMOs have limited experience in the technology transfer of manufacturing processes. 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 Bothell facility and the URMC site 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 will not know with certainty whether all relevant know-how and data has been adequately incorporated into the manufacturing process being conducted at our facility until the completion of studies and evaluations intended to demonstrate the comparability of material previously produced by our CDMOs with that generated by our facility.

Operating our Bothell facility and the URMC site will require us to comply with complex regulations. Moreover, the Bothell facility, and any future commercial manufacturing facilities we may operate, 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 inspections by the FDA, the Drug Enforcement Administration, corresponding state agencies, and comparable foreign regulatory authorities 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 to control costs, achieve scale, decrease processing time, increase manufacturing success rate, or for 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 any of our then-ongoing clinical trials or future clinical trials, or the performance of the product, once commercialized. In certain circumstances, if we make changes to our manufacturing process for a product candidate, regulatory authorities may require us to perform comparability studies and collect additional preclinical or clinical data prior to undertaking additional clinical trials or commercializing the relevant product candidate. For instance, if we make changes to our manufacturing process for a product candidate during the course of clinical development, regulatory authorities may require us to show the comparability of the product used in earlier clinical phases or earlier portions of a trial to the product used in later clinical phases or later portions of the trial. We may be unable to successfully generate comparability data, and even if we are able to generate and provide such data, regulatory authorities may determine that the data are insufficient to

support a determination of comparability, which could result in manufacturing delays and affect our ability to timely dose patients in our clinical trials, which could delay further development of such product candidate.

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 manufactured 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 or undertake additional clinical testing, either of which would significantly delay the clinical development or commercialization of the relevant product candidate.

Furthermore, if contaminants are discovered in our supply of product candidates or in our Bothell facility, the URMC site, 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 guarantee that any stability or other issues relating to the manufacture of our product candidates will not occur in the future. We may be unable to manufacture our product candidates if we fail to meet regulatory requirements and may be unable to scale up or scale out our manufacturing to meet market demand. Any failure or delay in the development of our manufacturing capabilities, including at the Bothell facility and at the URMC site, could adversely impact the development and potential commercialization of our product candidates.

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

We have experienced rapid growth since our inception in July 2018. As of September 30, 2022, we had 494 full-time employees and five part-time employees. We expect continued growth in 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, and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the complexity involved 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. The expansion of our operations will be costly and may divert our management and business development resources. For example, members of management will have significant added responsibilities in connection with effecting and managing our growth, including identifying, recruiting, integrating, maintaining, and motivating current and future employees, effectively managing our internal development efforts, including the clinical and regulatory (e.g., FDA) review process, while complying with our contractual obligations to third parties, and maintaining and improving our operational, financial, and management controls, reporting systems, and procedures. In addition, as we grow, we may be required to rely more heavily on third-party service providers, which exposes us to risks to which we would not be subject if we performed all work internally, as described elsewhere in these Risk Factors. Our inability to successfully manage our growth could delay the execution of our business plans or disrupt our operations.

***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 an inability to obtain suitable donor material from eligible and qualified human donors, restrictions on the use of human stem cells, as well as the 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 commercializing and gaining acceptance for our products derived from human stem cells.***

We use human stem cells in our research and development, including induced PSCs (iPSCs) and 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 numerous risks. These risks include difficulties in securing sufficient and viable stem cells as starting material, recruiting patients for our future clinical 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 significantly impaired, which could have a material adverse effect on our business. Further, the use of stem cells generally, and embryonic stem cells, in particular, 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 manufacturing. 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 any of our product candidates that may receive regulatory approval. In addition, clinical experience with stem cells, including 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 authority. Therefore, patients in our clinical trials may experience unexpected side effects, and we may experience unexpected regulatory delays prior to or, if approval were to be granted, after regulatory approval.

Furthermore, manufacturing and development of our *ex vivo* stem cell-derived and allogeneic T cell-derived product candidates will require that we obtain suitable donor material from eligible and qualified human donors. If we are unable to obtain sufficient quantities of suitable donor material, or if we are unable to obtain such material in a timely manner, we may experience delays in manufacturing our *ex vivo* product candidates, which would harm our ability to conduct future clinical trials for or to commercialize these product candidates. Moreover, if the consent, authorization, or process for the donation of those materials is not obtained or conducted in accordance with applicable legal, ethical, and regulatory requirements, we could face delays in the clinical testing and approval of these product candidates, or, potentially, we could face claims by such human donors, which could expose us to damages and reputational harm.

***The ongoing COVID-19 pandemic, or another pandemic, epidemic, or infectious disease outbreak in the United States or worldwide, could materially and adversely affect our preclinical studies and development, our manufacturing capabilities, any clinical trials we may commence, and our business, financial condition, and results of operations.***

As a result of the COVID-19 pandemic, or another pandemic, epidemic, or infectious disease outbreak, and related “shelter in place” orders and other public health guidance measures, we have experienced and may in the future experience disruptions that could materially and adversely impact our preclinical studies and development, any clinical trials we may commence, and our business, financial condition, and results of operations. In response to the spread of COVID-19, beginning in early 2020, we limited operations in our executive offices, with our administrative employees primarily working outside of our offices, and took other precautionary measures, including the periodic testing of our on-site employees and limiting employee travel. 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. Over time, consistent with the lifting of certain government orders and guidance, our staff have begun working in the offices more frequently, but many of our administrative employees continue to work outside of our offices on at least a part-time basis. We continue to monitor the effects of COVID-19 variants and subvariants, along with other infectious disease outbreaks, to assess the safety considerations associated with our employees working onsite and engaging in work-related travel.

With the return of employees to our offices, we face an increased productivity risk arising from the potential that they will be exposed to COVID-19 or other infectious diseases while onsite and will need to take time away from work to recover from any resulting illness. In addition, we require, with limited exceptions, all of our employees to be vaccinated against COVID-19, which may negatively impact our recruiting and retention efforts.

Potential disruptions to our preclinical development efforts resulting from the ongoing COVID-19 pandemic may include the following:

- 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 our CROs and vendors;

- limitations on employee or other resources that would otherwise be focused on the conduct of our preclinical activities, including because of illness 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 regulatory authorities, 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.

In addition, we have experienced, and we and our service providers or vendors may continue to experience, delays in the procurement of, or an inability to procure, certain laboratory supplies required for the conduct of our research and preclinical activities, such as cell culture plasticware and single use containers, as a result of factors related to the ongoing COVID-19 pandemic, including increased demand due to ramp up of COVID-19 research and manufacturing, government-mandated allocation of materials for such research and manufacturing, insufficient manufacturing capacity, and delays by CDMOs in increasing manufacturing capacity to address increased demand. The ongoing COVID-19 pandemic may also adversely affect our manufacturing capabilities. For example, we may experience delays or otherwise experience difficulties in building out and operationalizing the Bothell facility or the UPMC site and obtaining key materials, consumables, and equipment necessary to manufacture our product candidates.

In addition, if and when we commence clinical trials for any of our product candidates, we may experience potential delays or disruptions of clinical trial-related activities as a result of the ongoing COVID-19 pandemic, including as a result of the following:

- 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 staff;
- delays or difficulties in enrolling and retaining patients in our clinical trials;
- increased rates of patient withdrawal 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 toward efforts to support the COVID-19 pandemic response, including the diversion of resources, including staff, at hospitals serving as our clinical trial sites and supporting our clinical trials;
- interruption or delays in the operations of the FDA and comparable foreign regulatory agencies;
- changes in regulations implemented in response to the COVID-19 pandemic that 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 clinical trial-related activities, including because of illness 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 or other restrictions imposed in response to the COVID-19 pandemic in countries where we or our service providers operate.

The COVID-19 global pandemic continues to evolve, and the extent to which it may affect our preclinical studies, future clinical trials, business, financial condition, and results of operations will depend on future developments, which continue to be highly uncertain and unpredictable and present material uncertainty and risk to our business.

***Negative public opinion and increased regulatory scrutiny of research and therapies involving gene editing or other ex vivo or in 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 diseases that our product candidates are designed to target 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 of our product candidates. In addition, given the novel nature of *ex vivo* and *in vivo* cell engineering technologies, governments may impose 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**

***We must successfully progress our product candidates 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 future 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).

Preclinical and clinical testing is inherently unpredictable. We may obtain positive data from early research involving our product candidates but subsequently encounter unexpected or unexplained results in preclinical or clinical studies that may cause such product candidates to be unsuitable for further development. We may also need to perform additional research and preclinical or clinical studies to determine the cause of any unexpected results, including whether such results were caused by our product candidates or other factors, which could delay our development timelines or prevent us from continuing further development at all.

Even if we obtain positive results from preclinical studies of our product candidates, 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 successfully 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 any of our product candidates are prolonged or delayed, we may be unable to obtain required regulatory approvals and commercialize such product candidates on a timely basis or at all.***

Preclinical studies and clinical trials are expensive and can take many years to complete, and their outcomes are inherently uncertain. Failure can occur at any time during preclinical or clinical development. Product candidates in later-stage clinical trials may

fail to produce the same results as observed in earlier trials or fail 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.

Applicable laws and regulations require us to test our product candidates in animals before initiating clinical trials involving humans. We may experience delays in or experience difficulty completing studies of our product candidates in animals for various reasons. For example, due to global supply chain issues caused by global geo-political, economic, and other factors beyond our control, as described elsewhere in these Risk Factors, 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. In addition, 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 or delayed, or become more expensive.

We are required to submit an IND to the FDA with respect to each product candidate prior to commencing a clinical trial for such product candidate. While we plan to submit INDs for each of our product candidates, we may not be able to submit such INDs in accordance with our expected timelines for various reasons, including due to:

- manufacturing delays, including due to challenges associated with scaling up our manufacturing processes and developing and validating assays;
- delays in our IND-enabling preclinical studies; or
- feedback from the FDA that requires us to conduct additional testing or change the design of a planned clinical trial prior to submitting such IND.

Moreover, we cannot guarantee that submission of an IND for a product candidate will result in the FDA or comparable foreign regulatory authorities allowing clinical trials of that product candidate to commence in accordance with our timelines or expectations or at all. For example, the FDA may accept an IND submission for a product candidate but place clinical trials of such product candidate on hold pending the results of additional testing or the development of additional assays. 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.

To date, we have not commenced any clinical trials. 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 may be delayed, suspended, or terminated, or may not be able to be conducted at all, 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 clinical trial site;
- delays in or failure to reach agreement with prospective CROs and clinical trial sites on acceptable terms, or at all, which agreements 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 suitable donor material from eligible and qualified donors 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 inability to recruit and enroll suitable patients to participate in a trial, including as a result of study inclusion and exclusion criteria and patients' prior lines of therapy and treatment;
- the difficulty in certain countries in identifying the sub-populations that are the target group for 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 of patients to complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a trial;
- delays caused by the addition of new investigators or clinical trial sites;

- safety or tolerability concerns relating to the product candidate being tested that could cause us or governmental authorities, as applicable, to suspend or terminate a clinical 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 there is evidence that potential undesirable side effects or risks may be associated with another therapeutic or therapeutic candidate being developed by us or a third party and regulators deem our product candidate to have the potential for comparable side effects or risks as such therapeutic or therapeutic candidate because of biologic, mechanistic, sourcing, or other similarities;
- the failure of third-party contractors to comply with regulatory requirements or meet their contractual obligations 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, or failure to manufacture product candidates in accordance with cGMP and other applicable laws, regulations, and guidelines;
- changes in the treatment landscape for our target indications that may make our product candidates no longer relevant;
- claims that the product candidate being tested infringes third-party intellectual property rights, including any resulting injunctions that may prevent further use of such product candidates and interfere with the progress of the trial; and
- business interruptions resulting from geo-political actions, including war and terrorism, natural disasters including earthquakes, typhoons, floods, and fires, or disease, including the ongoing COVID-19 pandemic.

In addition, disruptions caused by the ongoing COVID-19 pandemic, to the extent it is still ongoing when we initiate our planned clinical trials, may increase the likelihood that we encounter difficulties or delays in initiating, enrolling, conducting, or completing such clinical trials, as described elsewhere in these Risk Factors.

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,” when those assessing and reviewing the physiological outcomes of patients in the clinical trials are aware of which patients have received the experimental treatment and may interpret the information of this 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.

Clinical trials must be conducted in accordance with the FDA’s and comparable foreign regulatory authorities’ legal requirements, regulations, and guidelines and are subject to oversight by these governmental authorities and IRBs or Ethics Committees of 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, including following an inspection of clinical trial operations or a clinical trial site, for a number of reasons, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from use of the product candidate being tested, or changes in governmental regulations or administrative actions. In addition, such authorities may impose a clinical hold on a product candidate due to unforeseen safety issues or adverse side effects that may be associated with another therapeutic or therapeutic candidate being developed by us or a third party if regulators deem our product candidate to have the potential for comparable side effects or risks as such therapeutic or therapeutic candidate because of biologic, mechanistic, sourcing, or other similarities. If we experience delays in completing, or are required to terminate, any clinical trial of our product candidates, the commercial prospects of the relevant product candidates will be harmed, and our ability to generate product revenues from 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 the relevant 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, which may impair our ability to commercialize our product candidates and harm our business and results of operations.

Furthermore, as described elsewhere in these Risk Factors, we will rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials in compliance with good clinical practices (GCP) requirements. 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 timely and successfully enroll patients in our clinical trials, fail to conduct such clinical trials in accordance with GCP,



or experience significant delays in the execution of trials, including delays in achieving full enrollment or clinical trial data collection and analysis, we may experience program delays, incur additional costs, or both, which may harm our business. In addition, we may experience delays and incur additional costs with respect to clinical trials that we conduct in countries outside the United States, including as a result of increased shipment and distribution costs, compliance with additional regulatory requirements, and the engagement of non-United States CROs, and may also be exposed to risks associated with clinical investigators who are unknown to the FDA, and different standards of diagnosis, screening, and medical care.

***We will depend on timely and successful 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 initiation and 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 the occurrence of adverse events. These types of developments could cause us to delay the trial or halt further development of the relevant product candidate.

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 participate in our trials, 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, and many patients who respond positively to the standard of care do not enroll in clinical trials. This may limit the number of eligible patients who have the potential to benefit from our product candidates and could extend development timelines or increase costs for our programs. Patients who fail to respond positively to the standard of care treatment would be eligible for clinical trials of our product candidates. However, treatment with prior regimens may render our product candidates less effective in clinical trials.

Because the number of qualified clinical investigators and clinical trial sites is limited, we expect to conduct at least some of our clinical trials at the same clinical trial sites as those used by our competitors, which will reduce the number of patients available to participate in our clinical trials at such clinical trial sites.

Patient enrollment in clinical trials depends on many factors, including:

- the size and nature of the patient population;
- the severity of the disease under investigation;
- eligibility and exclusion criteria for the trial;
- the number and location of clinical trial sites;
- the proximity of patients to clinical sites;
- the design of the clinical protocol;
- the ability to obtain and maintain patient consents;
- competition with other companies for clinical trial sites or patients;
- the perceived risks and benefits of the product candidate under evaluation, including any perceived risks associated with our product candidates;
- the ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the risk that enrolled patients will drop out of the trial before administration of our product candidate or trial completion;
- the availability of competing clinical trials;
- the availability of patients during the ongoing 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 product candidate being studied in relation to other available therapies, including any new therapies that may be approved for the indications we are investigating or the approved label expansion of an existing therapy into the indication we are investigating.

These factors may make it difficult for us to enroll enough patients to complete our clinical trials in a timely and cost-effective manner. If we are unable to timely recruit and enroll patients for our clinical trials, or if we are unable to enroll a sufficient number of patients necessary to complete our clinical trials as planned, we may be required to change our trial design, recruit and enroll a different population of patients than we anticipated, or recruit and enroll patients in geographies that are more challenging, and we may not be fully prepared to address such challenges. Delays in the completion of any clinical trial we may conduct will increase our costs, slow down the development and approval process, and delay or potentially jeopardize our ability to commence product sales and generate revenue for the relevant product candidate. In addition, some of the factors that may 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.

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

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.

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 authority involved. Prior to obtaining approval to commercialize our current or 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 experience delays in obtaining marketing approval, or we may not obtain approval at all. Additionally, any safety concerns observed in any one of our clinical trials for a product candidate in our targeted indications could limit the prospects for regulatory approval of such product candidate in those and other indications.

Even if we successfully complete any future clinical trials, clinical data are often susceptible to varying interpretations and analyses. 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. Even if positive results are observed in clinical trials, we cannot guarantee that the FDA or comparable foreign regulatory authorities will view our product candidates as having efficacy. Further, the FDA or comparable foreign regulatory authorities may not agree with our manufacturing strategy or may not find comparability between our clinical trial product candidates and proposed commercial product candidates, which may result in regulatory delays or a need to perform additional clinical studies. Moreover, clinical trial results that may be acceptable to support approval of a certain scope in one jurisdiction may be deemed inadequate to support regulatory approval, or may only be deemed sufficient to support a narrower scope of approval, in other jurisdictions. If the FDA or comparable foreign regulatory authorities determine that our clinical trial results are not adequate to support approval of a marketing application, we may experience delays in obtaining, or fail to obtain, approval of our product candidates, 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 obtained 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.

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

Our product candidates may cause undesirable side effects, which could cause us or regulatory authorities to interrupt, delay, or halt our future 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 or other information that would enable us to fully anticipate their side effects. Accordingly, we may observe unexpected side effects or higher levels of known side effects in clinical trials of our product candidates, including adverse events known to occur in the same classes of therapeutics. These may include, 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 associated with our product candidates. In such an event, clinical trials of such product candidates 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 such product candidates for any or all targeted indications. The occurrence of such side effects could negatively affect our ability to recruit and enroll patients in our clinical trials, or the ability of enrolled patients to complete the clinical trials or result in product liability claims. Any of these occurrences could significantly harm our business, financial condition, and prospects.

Further, clinical trials by their nature utilize only a sample of the potential patient population. With a limited number of patients and limited duration of exposure to our product candidates, rare and severe side effects of our product candidates may not be apparent during early clinical trials and may only be uncovered once a significantly larger number of patients have been exposed to the product candidate, including during later-stage clinical trials or following commercialization.

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 products off the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, or 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 therapeutic 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.

***Interim, topline, or preliminary data from our preclinical studies or future clinical trials that we may announce or publish from time to time may change as more data become available or as we make changes to our manufacturing processes. These data 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 or future 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 at the time of our initial disclosure of data. Further, modifications or improvements to our manufacturing processes for a product candidate may result in changes to its characteristics or behavior that could cause the 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 disclosed. 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 our competitors, with respect to clinical trials of their product candidates, could result in volatility in the price of our common stock.

Further, others, including regulatory authorities, 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 our potential product candidates may be harmed, which could harm our business, operating results, prospects, or financial condition.

***The manufacture of our product candidates is complex. We or our CDMOs 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. As described elsewhere in these Risk Factors, we have entered a long-term lease to establish a manufacturing facility in Bothell, Washington and have entered into an agreement with URMC, pursuant to which we have obtained access to manufacturing capabilities within URMC's cell-based manufacturing facility. We expect that it will take at least several years before we are able to begin manufacturing our product candidates at the Bothell facility, if at all. We currently rely, and expect for some period of time to continue to rely, on CDMOs for the manufacture of certain of our product candidates for preclinical and clinical studies. Moreover, as described elsewhere in these Risk Factors, given our decision to move our planned manufacturing from the Fremont facility to the Bothell facility, it may take us longer to establish and operationalize our internal manufacturing facility than we originally anticipated, which may delay our ability to begin manufacturing certain of our product candidates internally and extend how long we need to rely on CDMOs for the manufacture of such product candidates. To date, we and our CDMOs have limited experience in manufacturing of cGMP batches of our product candidates. Our CDMOs and, once we begin to operate the Bothell facility and the URMC site, we, must comply with cGMPs and other regulations and guidelines applicable to the manufacturing of biologics for use in clinical trials and, if approved, commercial sale. To date, we have not scaled the manufacturing processes 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 CDMOs or the technologies that our CDMOs incorporate into our manufacturing processes will result in viable or scalable yields of *ex vivo* and *in vivo* cell engineering product candidates that will be safe and effective and, if approved, meet market demand.

Once we have completed the build-out of the Bothell facility, we will be required to transition manufacturing processes and know-how of certain of our product candidates to this facility. To date, we and our CDMOs have limited experience in the technology transfer of manufacturing processes. 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. We may also need to conduct additional studies to support the transfer of certain manufacturing processes and process improvements. We will not know with certainty whether all relevant know-how and data have been adequately incorporated into the manufacturing process being conducted at our facility until the completion of studies and evaluations intended to demonstrate the comparability of material previously produced by our CDMOs with that generated by our facility.

Our biologic product candidates are susceptible to product loss or reduced manufacturing success rates at various points during the manufacturing process, including due to contamination, equipment damage or failure, including during shipment or storage, failure of equipment to operate as expected, improper installation or operation of equipment, vendor or operator error, damage to, variability of, or improper use of raw materials or consumables necessary for the manufacturing process, inconsistency in yields, variability in product characteristics, and difficulties in scaling the production process. Any of these issues, and even minor deviations from normal manufacturing processes, could result in reduced production yields, product defects, and other supply disruptions and delays. 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, if approved, 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 CDMOs are not in compliance with applicable laws and regulations, including cGMPs, the FDA or comparable foreign regulatory authority may not approve a biologics license application (BLA) or comparable foreign marketing authorization until the deficiencies are corrected or we replace the manufacturer

in our applications with a manufacturer that is in compliance. If we or our CDMOs fail to comply with applicable regulatory requirements, we may ultimately be unable to manufacture our product candidates. The occurrence of any of these issues could delay our ability to commence or timely complete clinical development, obtain regulatory approval of, and commercialize our product candidates.

Any adverse developments affecting manufacturing operations for any of our product candidates, including those for which we may obtain regulatory approval, may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other supply interruptions that could negatively impact the conduct of our clinical trials or our ability to successfully commercialize any product candidates for which we may obtain regulatory approval. 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, as described elsewhere in these Risk Factors, we also may make changes to our manufacturing processes at various points during development for various reasons, such as to control costs, achieve scale, decrease processing time, increase manufacturing success rate, or for other reasons. Such changes may not achieve their intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of our future clinical trials. In some circumstances, changes in the manufacturing process for a product candidate may require us to perform comparability studies and collect additional data from patients prior to undertaking additional clinical trials or obtaining regulatory approval of that product candidate.

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

Manufacturing our product candidates is highly complex and requires sourcing of specialty materials. Many of the risks associated with the complexity of manufacturing our final product candidates are applicable to the manufacture and supply of the raw materials required to make such product candidates. In particular, these raw 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 raw materials could result in supply disruption and reduced production yields for our final product candidates. In addition, we rely on third parties for the supply of these materials, which exposes us to risks associated with dependence on third parties, as described elsewhere in these Risk Factors.

We must obtain suitable donor material from eligible and qualified donors for the manufacture of product candidates from our *ex vivo* cell engineering platform. We may not be able to obtain sufficient quantities donor material in a timely manner or at all, including if we are unable to find donors who meet the eligibility criteria or as a result of geo-political, economic, and other factors beyond our control that may prevent individuals from donating blood. If we are unable to obtain sufficient quantities of suitable donor material, or if we are unable to obtain such material in a timely manner, we may experience delays in manufacturing our *ex vivo* product candidates, which would harm our ability to conduct future clinical trials of or to commercialize these product candidates.

In addition, we require 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, for our manufacturing processes and for quality control testing of our product candidates, some of which are manufactured or supplied by small companies with limited resources and experience with respect to supporting clinical or 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 manufacturing of products under cGMP 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 enter into 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, materials, and equipment, we currently rely and may in the future rely on sole source vendors or a limited number of vendors. We may be unable to continue to source reagents, materials, or equipment from any of these suppliers for various reasons, including due to regulatory actions or requirements affecting a supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demand from other customers and supply limitations, or quality issues. Additionally, due to global geo-political, economic, and other factors beyond our control, 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, which could affect our or our CDMOs' ability to obtain the materials and equipment necessary to manufacture our product candidates. If any of the foregoing events were to occur, we may experience delays in manufacturing our product candidates, which would harm our ability to conduct future clinical trials and, if approved, commercialize our product candidates and generate product revenues in a timely manner or at all.

Additionally, as described elsewhere in these Risk Factors, rising rates of inflation have resulted in substantial increases in the costs associated with manufacturing our product candidates that we are unable to offset. Given the unpredictable nature of the current

economic climate, including future rates of inflation, it may be increasingly difficult for us to predict and control our future expenses, which may harm our ability to conduct our business.

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

***We may become exposed to costly and damaging liability claims, either when testing our product candidates in clinical trials or at the commercial stage, and our product liability insurance may not cover all damages arising 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 product candidates for which we have commenced clinical trials or obtained approval for commercial sale, the future use of our product candidates in clinical trials, and the sale of any products for which we may obtain approval 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. Physicians and patients may not comply with any warnings that identify known potential adverse effects or patients who should not use our product candidates. 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.

We would require significant financial and management resources to defend against any product liability claims, even if we are successful in such defense. Regardless of the merits or eventual outcome, liability claims may result in decreased demand for our product candidates, negative publicity and injury to our reputation, withdrawal of clinical trial participants, initiation of investigations by regulatory authorities, costs to defend the related litigation, diversion of management's time and our resources, substantial monetary awards to clinical 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, inability to commercialize our product candidates, and a decline in our share price.

Although we maintain 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 Dependence on Third Parties**

***We rely on, and expect to continue to expect to rely on, CDMOs, including third-party testing laboratories, to manufacture our product candidates, as well as materials used in the manufacturing of our product candidates, including testing of such product candidates and materials. Any failure by a CDMO to properly produce acceptable materials or product candidates for us or any failure by us or such CDMO to obtain authorization from the FDA or comparable foreign regulatory authorities or otherwise satisfy regulatory requirements with respect to such manufacturing of our product candidates 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. As described elsewhere in these Risk Factors, in June 2022, we entered into a long-term lease to establish and develop our cGMP manufacturing facility at the Bothell facility. Until we are able to begin manufacturing our product candidates at the Bothell facility, we will rely in part on CDMOs, including third-party testing laboratories, to manufacture our product candidates for use in preclinical and clinical testing and will continue to rely on such CDMOs to manufacture certain of our product candidates thereafter as part of our manufacturing strategy. As described elsewhere in these Risk Factors, given the move of our planned manufacturing to the Bothell facility from the Fremont facility, it may take us longer to establish and operationalize our manufacturing facility than we

originally anticipated, which may delay our ability to begin manufacturing certain of our product candidates internally and extend how long we need rely on CDMOs for the manufacture of such product candidates.

A limited number of CDMOs specialize in or have the expertise required to manufacture our product candidates. Moreover, our CDMOs 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 CDMOs 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 CDMOs face intense competition to attract and retain qualified personnel. If our CDMOs 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. Further, as described elsewhere in these Risk Factors, there are few alternatives for the CDMOs that we currently engage, and even if one of our CDMOs fails to perform according to our expectations and we decide to switch to an alternative CDMO, there is no guarantee that such alternative CDMO will be able to perform its obligations in a timely manner or that its performance will meet our expectations or quality requirements. Any delays in manufacturing our product candidates could materially harm our ability to conduct our clinical trials or commercialize our product candidates in a timely manner or at all and could harm our business.

In addition, we rely on multiple CDMOs to produce sufficient quantities of materials required for the manufacture of our product candidates for preclinical testing and future clinical trials, and intend to continue to rely on such CDMOs for the commercial manufacture of certain of our products, if approved. Global supply chain shortages and rising rates of inflation have resulted in substantial increases in the costs of materials, including raw materials, reagents, consumables, and equipment that are required to make or used in the manufacture of our product candidates. If we are unable to obtain such items from third-party sources, or fail to do so on commercially reasonable terms, we may not be able to produce sufficient supply of product candidate or we may be delayed in doing so. Such inability or failure, or any substantial delay in obtaining such items, 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 our product specifications. If these materials do not comply with our product specifications, or in the event of any other disruption in the supply of these materials, our business could be materially adversely affected. 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 low yield from certain manufacturing batches, which could 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 these materials or product candidates generated using such materials.

Reliance on CDMOs entails additional risks to which we would not be subject if we manufactured product candidates ourselves, including those applicable to other third-party service providers, as described elsewhere in these Risk Factors. In particular, such risks include reliance on the CDMO for regulatory compliance and quality control and assurance, volume production, the possibility of breach of the manufacturing agreement by the CDMO due to 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 CDMO 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 cGMP requirements and similar foreign standards relating to methods, facilities, and controls used in the manufacturing, processing, and packing of the product candidate, 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 CDMO'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, on a timely basis or at all. Any discovery of problems with a product, or a manufacturing or laboratory facility used by us or our strategic partners in connection with manufacturing of that product, may result in restrictions on the product or on the relevant 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 any such incidents at our CDMOs.

If we were unable to timely find an adequate replacement for our CDMOs or another acceptable solution, our clinical trials could be delayed, or our commercial activities could be harmed. In addition, because we are dependent on our collaborators, our suppliers, and other third parties for the manufacture, filling, storage, and distribution of our product candidates, we have limited

ability to prevent or control manufacturing defects in our products. The sale of products containing such defects could adversely affect our business, financial condition, and results of operations. Any failure by our CDMOs to comply with cGMP or failure to properly scale-up manufacturing processes for our product candidates, or 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 a product is marketed, which includes periodic unannounced and announced inspections by the FDA to assess compliance with cGMP requirements. Any failure by one of our CDMOs 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 CDMO to address any concerns raised by the FDA or comparable foreign regulatory authorities could also lead to plant shutdown or the delay or withholding of product approval by the FDA in additional indications or by comparable foreign regulatory authorities 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 CDMOs 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 interruptions or difficulties, we may be unable to resume supply of such materials or other manufacturing activities within a reasonable time frame and at an acceptable cost or at all, which would adversely affect our business.***

The manufacture of our product candidates requires the timely delivery of sufficient amounts of raw and intermediate materials. We purchase, and rely on our CDMOs to purchase, certain of these materials from third-party suppliers in order to produce our product candidates for our preclinical studies. There are a limited number of suppliers of these materials, and we may need to assess alternate suppliers to prevent possible disruption of manufacturing of our product candidates for our preclinical studies, our future clinical trials, and if ultimately approved, commercial sale. We intend to continue to rely on our CDMOs to purchase materials in order to produce product candidates for any clinical trials that we undertake; however, we do not have any control over the process or timing of the acquisition of these materials by our CDMOs or the costs of such materials. We work closely with our CDMOs and suppliers, as applicable, to ensure the continuity of supply, but we cannot ensure that these efforts will always be successful. Further, while we strive to diversify our sources of raw and intermediate materials, in certain instances we acquire raw and intermediate materials from a sole supplier. 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 supply 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 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 would 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 or intermediate 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. While we believe that alternative sources of supply exist when we rely on sole supplier relationships, we cannot ensure that, if needed, we would be able to quickly establish additional or replacement sources for some materials. Moreover, we currently do not have any agreements for the commercial production of these raw or intermediate materials. If any of our product candidates receives regulatory approval and thereafter, we or our CDMOs are unable to purchase these raw or intermediate materials, the commercial launch of our product candidates could be delayed or there could be a shortage in supply of product, which would impair our ability to generate revenues from the sale of such approved product. A reduction or interruption in supply of raw or intermediate materials, and an inability to establish alternative sources for such supply, could adversely affect our ability to manufacture our product candidates or approved products in a timely or cost-effective manner.

***We rely, and expect to continue to rely, on third parties, including independent clinical investigators, CROs, and other service providers, 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, CROs, and other service providers, to conduct or support our preclinical studies and clinical trials and related activities, and to monitor and manage data for our ongoing preclinical and clinical programs. We rely or will rely on these parties for execution of our preclinical studies and clinical trials and related activities needed to support such studies and trials, and control only certain aspects of their activities. Even then, we are only able to control such activities to the extent set forth under our contracts with the relevant third parties. Nevertheless, we are responsible for ensuring that each of our preclinical and clinical studies and trials is conducted in accordance with the applicable protocol and legal, regulatory, and scientific standards and rules, and our reliance on these third parties



does not relieve us of these obligations. With respect to any of our product candidates that may enter clinical development, we and our third-party contractors and CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities. Regulatory authorities enforce these GCPs through periodic inspections of clinical trial sponsors, principal investigators, and clinical trial sites. If we or any of our CROs, or any principal investigators or clinical trial sites involved in our trials, fail to comply with applicable GCPs, the clinical data generated from these 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 be certain that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process for the relevant product candidate.

Further, third parties that support our preclinical and clinical programs, such as principal investigators, clinical trial sites, and CROs, are not our employees, and we are unable to control, other than by contract, the amount of resources, including time, that they devote to our product candidates and clinical trials. If such third parties, including our CROs or other service providers, 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 such third parties 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 such product candidates. In addition, in order for these third parties to perform under their contracts with us, we regularly disclose or plan to disclose to these third parties confidential or proprietary information, which increases the risk that this information will be misappropriated. Additionally, disruptions caused by global geo-political, economic, and other factors beyond our control may increase the likelihood that these third parties encounter difficulties or delays in performing their obligations to us, including with respect to initiating, enrolling, conducting, or completing our planned clinical trials.

Third parties, including our CROs, generally have the right to terminate their agreements with us in the event of an uncured material breach by us. In addition, certain third parties may have the right to terminate their respective agreements with us under other circumstances, including 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 parties, including service providers and clinical trial sites, that specialize in or have the expertise required to achieve our business objectives. If any of our relationships with these third parties, including laboratories, CROs, or clinical trial sites, terminate, we may not be able to enter into arrangements with alternative third parties or to do so in a timely manner or on commercially reasonable terms. If these third parties 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 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 from existing service providers or clinical trial sites, or adding additional service providers or clinical trial sites, involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new service provider commences work. As a result, delays can occur, which may materially impact our ability to meet our desired development, including clinical development, timelines. Additionally, service providers may lack the capacity to absorb higher workloads or take on additional capacity to support our needs. Though we carefully manage our relationships with these service providers, including our contracted laboratories and CROs, there can be no assurance that we will not encounter these types of 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 conduct or interpretation of one of our preclinical studies or clinical trials, the integrity of the data generated from such preclinical study or clinical trial may be questioned and the utility of the preclinical study or clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA of any regulatory submissions related to our product candidates. Any such delay or rejection could prevent us from commercializing our product candidates.

## **Risks Related to Intellectual Property and Information Technology**

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

Patent rights are national or regional rights. The filing, prosecution, maintenance, and defense of patent rights on our platform technologies and product candidates worldwide would be prohibitively expensive, and our intellectual property rights in some

countries outside the United States may 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 intellectual property rights in all countries outside the United States or from making, using, selling, or importing products made using our intellectual property rights in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained intellectual property rights, including patent protection, to develop their own products and may also export otherwise infringing products to territories where we have intellectual property rights, including patent protection, but enforcement rights are not as strong as those in the United States. These products may compete with our products and our patent 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 are expensive, especially in jurisdictions where we have no local presence, and 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, or 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 lasts for years before it is 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/or 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 may 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 initiate or continue our future 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 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 depend on patents, know-how, and proprietary technology, both that we own and that we license from others to research, develop, and commercialize our product candidates. We are a party to a number of intellectual property license agreements and acquisition agreements pursuant to which we have acquired certain of 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 for 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 or 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 such fields of use or territories. 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. These license and acquisition agreements impose, and we expect that future license and acquisition agreements will impose, various diligence, milestone and royalty payment, 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 agreement. 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, or commercialize one of our product candidates. See the subsection titled “Business— Key Intellectual Property Agreements” in Part I, Item 1 of our Annual Report on Form 10-K as filed with the SEC on March 16, 2022 (2021 Annual Report) 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 would also suffer if any current or future licensors fail to abide by the terms of the license, if such 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 product candidates that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize any product candidates, we may be unable to achieve or maintain profitability.

If we are unable to successfully 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 issues related to interpretation of the agreement;
- 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 the patent and other rights granted to us under the license agreement to third parties as part of collaborative development relationships;
- whether we are complying with our diligence obligations with respect to the use of the licensed intellectual property rights 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 properly and timely conduct these activities for patents or patent applications covering any of our product candidates, 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 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, these 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 could cause us to lose rights to intellectual property that we may need to operate our business or could cause us to lose the ability to exclude our competitors from using the intellectual property rights. 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 contractual obligations to our licensors related to such prosecution, we may incur significant liability to our licensors.

***We may not be successful in obtaining or maintaining necessary rights to product candidates, product candidate components, or processes for our product development pipeline, which may require us to operate our business in a more costly or otherwise adverse manner than we anticipated. We may not be successful in obtaining or maintaining exclusive rights to owned and in-licensed patents or patent applications or future patents to the extent they are co-owned with third parties.***

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. If we are unable to do so, we may be required to expend considerable time and resources to develop or license replacement technology. For example, our programs may rely upon additional technologies or product candidates that require the use of additional proprietary rights held by third parties. Furthermore, other pharmaceutical companies and academic institutions may have filed or may plan to file patent applications potentially relevant to our business. In order to work effectively and efficiently, our product candidates may also require specific formulations or other technology, which may be covered by intellectual property rights held by others. From time to time, in order to avoid infringing third-party patents, we may be required to license technology from these third parties to further develop or commercialize our product candidates. We may be unable to acquire or in-license third-party intellectual property rights that we identify as necessary or important to our business operations, including those required to make, use, or sell our product candidates. 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. In addition, may need to seek to develop alternative approaches that do not infringe on such intellectual property rights, which, if we were successful in developing such alternatives, may entail additional costs and lead to delays in development. In certain cases, it may not be feasible for us to develop such alternatives. Even if we are able to obtain a license under such intellectual property rights, any such license may be non-exclusive, which may allow our competitors to access to the same technologies licensed to us.

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

The licensing and acquisition of third-party intellectual property rights is competitive, 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 negotiations and ultimately license or acquire the rights to the intellectual property necessary or useful for the development of our product candidates.

Our product candidates may also require specific components to work effectively and efficiently, and rights to those components may be held by third parties. We may be unable to in-license any compositions, methods of use, processes, or other intellectual property rights from any such third parties that we identify, including because such licenses may not be available 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-owner's interest in such patents or patent applications, such co-owner may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technologies. In addition, we may need the cooperation of any such co-owner 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 depend 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 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* and *in vivo* cell engineering platforms has been funded at least in part by the United States 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 rights 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 United States industry, which may limit our ability to contract with foreign product manufacturers for products covered by such intellectual property rights. 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 in-license technology that is critical to our business and is developed in whole or in part with federal funds subject to the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected.

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

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

- if and when any patents will issue;

- the degree and range of protection any issued patents will afford us against competitors, including whether third parties will find ways to invalidate or otherwise circumvent our patents;
- whether others will apply for or obtain patents claiming inventions 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 we and our licensors may not be able to prosecute, all necessary or desirable patent applications or maintain, defend, 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 or before another party files a patent application covering the relevant inventions. Although we enter into confidentiality agreements with parties that 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 products such as *ex vivo* and *in 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 United States Patent and Trademark Office (USPTO), or by patent agencies 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 products 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 may be difficult to prevent or prosecute.

One aspect of the determination of patentability of inventions depends on the scope and content of the "prior art," which is 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 inventions 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 on the patentability of our own patents and patent applications, as well as upon our freedom to operate, is highly uncertain. Because patent applications in the United States and most other countries are typically confidential for 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 United States patent 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 United States patent 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 Leahy-Smith America Invents Act (the Leahy-Smith Act), which introduced significant changes to the United States patent laws, including new procedures for challenging pending patent applications and issued patents.

The strength of patents in the biotechnology and pharmaceutical fields can be uncertain and evaluating the scope and validity of such patents involves complex legal, factual, and scientific analyses, which may vary based on the jurisdiction in which the analyses are performed. Patents have in recent years been the subject of much litigation in the United States and worldwide, resulting in court decisions, including United States Supreme Court decisions, that have increased uncertainties as to the patentability of certain inventions as well as the enforceability of 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 platform technologies or 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 patentability, validity, enforceability, or scope thereof, which may result in such patents being narrowed, invalidated, revoked, 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 patentable by administrative bodies or valid by courts in either 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 filings we hold with respect to our platform technologies or our product candidates is threatened, this could dissuade companies from collaborating with us to develop, and could threaten our ability to successfully 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, as patent rights are time limited, 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 or validity 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 worldwide, including in the United States, that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. The scope of a patent's claims is determined by an interpretation of the laws of the country in which the patent has been granted, the written disclosure in the 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 worldwide, including in the United States, 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.

***Intellectual property rights do not necessarily protect us from 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 certain issued patents or pending patent applications 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;
- our pending patent applications may not lead to issued patents;
- issued patents that we own or have exclusively licensed may be revoked or may be held invalid, unpatentable, or unenforceable, including as a result of legal challenges;
- 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 that may issue 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 that may issue based on our patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties;
- if we seek to enforce our patents, a court may not hold that our patents are valid, enforceable, or infringed;
- we may need to initiate litigation or administrative proceedings to enforce or defend our patent rights, which will be costly regardless of outcome;

- we may choose not to file a patent in order to maintain certain rights as 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 patent rights 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 rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, subject matter for which patents are difficult to enforce, and other elements of our product candidates, technology, and product discovery and development processes that involve proprietary know-how, information, or technology that we do not cover through patent protection. Any disclosure, either intentional or unintentional, by our current or former employees, contractors, collaborators, or those of third parties, including those with whom we share our facilities and 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 or confidential 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, 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, can 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 or confidential information, including our technology and processes. Although we use reasonable efforts to protect our trade secrets and confidential information, our employees, consultants, outside scientific advisors, contractors, and collaborators might intentionally or inadvertently disclose such information to competitors, including, as to consultants and advisors, to their primary employers, in breach of our agreements with such parties, and adequate remedies for such breaches may be unavailable. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties or misappropriation of our intellectual property by third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results, and financial condition.

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

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. We cannot be certain that our platform technologies, product candidates, and other proprietary technologies we may develop will not infringe existing or future patents owned by third parties. The legal and administrative landscape related to infringement of the patents and proprietary rights of third parties is fluid as 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. These include interference, derivation, *inter partes* review, post-grant review, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. Litigation and other legal proceedings relating to intellectual property claims, with or without merit, are unpredictable and generally expensive and time-consuming and, even if resolved in our favor, are likely to divert significant resources from our core business and distract our technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, 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 enter into or compete in the marketplace. Furthermore, patent reform and changes to patent laws add uncertainty to the possibility of challenge to our patents in the future.

Numerous issued patents and pending patent applications owned by third parties may exist worldwide in the fields in which we are developing our platform technologies and product candidates. We cannot provide any assurances that third-party patent filings that might be enforced against the making, use, or sale of our current product candidates or future products do not exist, which, if they did exist, would result in either an injunction prohibiting our sales, or an obligation to pay royalties on product sales 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 will be subject 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 patent filings of which we are currently unaware with claims, including claims to compositions, formulations, methods of manufacture, or methods of use or treatment, that cover our product candidates. It is also possible that patent filings owned by third parties of which we are aware, but which we do not believe are relevant to our platform technologies, product candidates, or other proprietary technologies we may develop, could be found to be infringed by our product candidates. Because patent applications can take many years to issue, there may be pending patent applications, including those of which we are unaware, that may later result in issued patents that our product candidates may infringe. In addition, third parties, including 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, use, sell, 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 unpatentable, invalid, or unenforceable. Such a license may not be available on commercially reasonable terms or may not be available 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 the making, use, or sale of various types of products or methods of use. The scope of patent coverage is subject to interpretation by both administrative bodies and the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that the making, use, or sale of 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 would invalidate the claims of any such patent. We may not have sufficient resources to bring these actions to a successful conclusion. Even if we are successful in these proceedings, they could cause us to incur substantial costs and divert the time and attention of our management and scientific personnel, which could have a material adverse effect on our business and operations.

Third parties asserting their patent or other intellectual property rights, such as confidential information or trade secrets, 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 against these claims, regardless of their merit, would involve substantial litigation expense and could divert management and other employee resources from our business, cause development delays, and 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 to do 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.

***Issued patents and patent applications covering our platform technologies, product candidates, components, or processes in our product development pipeline could be found unpatentable, invalid, or unenforceable if challenged in courts worldwide, including in the United States, or before an administrative body such as the USPTO or comparable foreign authority.***

Our issued patents or pending patent applications may be challenged in the courts or patent offices in the United States and abroad. For example, our patent applications may be subject to a third-party pre-issuance submission of prior art to the USPTO, or we may become involved in post-grant review proceedings, opposition or derivation proceedings, 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 proceeding may result in loss of exclusivity or in our patent claims being narrowed, invalidated, held unpatentable, or held unenforceable, in whole or in part, which could limit our ability to exclude others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products, and otherwise no longer protect our product candidates.

In addition, if we or one of our licensing partners initiates legal proceedings against a third party to enforce a patent covering one of platform technologies or one of our product candidates, the defendant could counterclaim that 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 or abroad, 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, using post-grant proceedings such as re-examination, *inter partes* review, post-grant review, opposition, or derivation proceedings. The outcome following legal assertions of unpatentability, invalidity, or unenforceability is unpredictable. In a proceeding before an administrative body, there is a risk that the body will decide that a patent is unpatentable or will be revoked, in whole or in part. 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. In the event of either decision, we would not have the right to stop another party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court or administrative body 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. The courts could also 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 and patentability 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 offices were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection for the relevant product candidate, which could limit our ability to assert our patents against those parties or other competitors and prevent us from excluding third parties from making, using, or selling similar or competitive products. 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.

***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 could 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 patents issue 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 require 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 of our or our licensors' intellectual property, 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, the price of our common stock could be substantially adversely affected.

***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.***

The USPTO and foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar requirements during the patent application process. Additionally, periodic maintenance fees on any issued patent must be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in a failure to perfect a priority claim, 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 terms of our patents may not be sufficient to effectively protect our products and business.***

Patents have limited terms, and in many jurisdictions worldwide, including the United States, if all maintenance fees are timely paid, the natural expiration of a patent's term is generally 20 years after its first effective nonprovisional filing date. Although various extensions may be available, the term of a patent, and the protection it affords, is limited. Given the significant amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. 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. 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 therapies. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours. Our patents issued as of October 2022 have terms expected to expire on dates ranging from 2023 to 2041, subject to any patent extensions that may be available for such patents. If patents are issued on our patent applications pending as of October 2022, the resulting patents are projected to expire on dates ranging from 2023 to 2043. In addition, although upon issuance in the United States a patent's term 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 also be available in the United States and in certain other foreign jurisdictions. However, in the United States, 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 in the United States does not extend to the full scope of the patent's claims, but instead only as to the scope of the product as approved. The laws governing analogous patent term extensions in foreign jurisdictions vary widely and many differ from the process in the United States. Additionally, we may not receive an extension of patent term if we fail to exercise due diligence during the testing phase or regulatory review process, fail to 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 the term of any such extension is less than we request, the period during which we will have the right to exclude others from using the patent rights will be shortened. Our competitors may be able to obtain approval of competing products following our patent expiration and take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to launch a biosimilar product earlier than might otherwise be the case, which could reduce our revenue, possibly materially. In general, if we do not have sufficient patent term to protect our platform technologies and product candidates, our business and results of operations will be adversely affected.

***We may be subject to claims challenging the inventorship or ownership of our patent and other intellectual property rights.***

We may be subject to claims that former employees, collaborators, or other third parties have an ownership interest in our patents or other intellectual property, including as a result of being an inventor or co-inventor. In the United States, the failure to name the proper inventors on a granted patent can result in the patent being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions made to an invention by the 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, inventorship disputes may arise from conflicting obligations of consultants or others who are involved in developing our platform technologies or product candidates or related intellectual property. 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 claims challenging or

relating to inventorship and ownership of intellectual property rights. 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 the 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 distract 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 United States government, such that we or our licensors are not the sole and exclusive owners of the patents that we own or that we have in-licensed. If 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 make, use, or sell 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. As described elsewhere in these Risk Factors, such claims could be expensive and time-consuming to litigate or defend and could divert the time and attention of our management and scientific personnel, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

***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 by other organizations, including at other biotechnology or pharmaceutical companies or at academic institutions. We may be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise improperly 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 cause us to incur substantial costs and distract 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 these third parties or former employers. Moreover, any such litigation or the threat thereof may adversely affect our reputation and 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.

***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 trade secrets or other 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 vendors that have access to our confidential information, including third-party vendors of information technology 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 of or unauthorized access to confidential information, including those involving acts by current or former employees, third-party service providers (including providers of information technology-specific services), nation states (including groups associated with or supported by foreign intelligence agencies), organized crime organizations, "hacktivists," or others. One third-party vendor that experienced such an incident 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. In addition, the current geo-political climate and tensions between the United States and certain countries, including Russia and China, may increase our vulnerability to such cybersecurity attacks. For example, in July 2022, the heads of the Federal Bureau of Investigation and MI5 issued joint warnings regarding the threat posed by China to national security in the United States, United Kingdom, and allies in Europe and globally due to the Chinese government's increasing use of cyber espionage to steal technology from Western corporations and disrupt Western business. Moreover, the biotechnology industry is one of the top industries that China has targeted for domestic growth and development, and it therefore may be a primary target for such cyber espionage efforts. We continue to monitor our systems and upgrade our security capabilities in order to mitigate risk. However, any access to or loss or theft of our confidential information in connection with a future cyberattack could have a material adverse effect on our business.

Threats involving the misuse of access our network, systems, and information by our current or former employees, contractors, vendors, or partners, whether intentional or unintentional, also pose a risk to the security of our network, systems, and information and data. For example, we are subject to the risk that employees may inadvertently share confidential information with unintended third parties, or that departing employees may take, or create their own information based on, our confidential information upon leaving the company. In addition, any such insiders may be the victims of social engineering attacks that enable third parties to access our network, systems, and information using an authorized person's credentials. We and our network, systems, and information are also vulnerable to malicious acts by insiders, including leaking, modifying, or deleting confidential information, or performing other acts that could materially interfere with our operations and business. While we provide regular training to our employees regarding cybersecurity threats and best practices, we cannot ensure that such training or other efforts will prevent unauthorized access to or sabotage of our network, systems, and information.

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 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, it could materially disrupt our operations and programs, and the development of our product candidates could be delayed. 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 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. As a result, we could incur significant legal and financial exposure and reputational damages that could have a material adverse effect on our business.

In addition, we have and will continue to enter into collaboration, license, contract research, and manufacturing relationships with 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. If any theft affects our technology, data, or intellectual property, our efforts to protect and enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from our intellectual property, 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 destroys the proprietary nature of our intellectual property.

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

Our current or future trademarks or trade names may be challenged, infringed, circumvented, or declared generic or descriptive, or may be determined to infringe 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 trademarks or trade names, which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, our applications may be rejected by the USPTO or comparable agencies in 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 collaborators or 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 may propose to use as a trade name for any of our product candidates in the United States must be approved by the FDA, regardless of whether we have 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 a comparable foreign regulatory authority objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would be registerable 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 trademarks or trade names similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trademark or trade name 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.

***Changes in United States 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 patent rights. 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 protection of, and may diminish our ability to protect, our inventions and obtain, maintain, and enforce our intellectual property rights and, more generally, could adversely 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 Act signed into law on September 16, 2011, could increase uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act introduced a number of significant changes to United States 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 patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack patents by USPTO-administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. In addition, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system for filings made after March 2013 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 requires us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our platform technologies, product candidates, and other proprietary technologies we may develop or (ii) invent any of the inventions claimed in our or our licensors' 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 if 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. 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.

In addition, recent United States 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 United States 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.

## 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 unable to obtain regulatory approval for our product candidates on a timely basis, or 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 activities we may engage in 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 will not be permitted to market any product candidate in the United States until the FDA has approved 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.

To date, we have not submitted a BLA to the FDA or similar regulatory approval filings to comparable foreign regulatory authorities for any product candidate, and we cannot be certain that any of our product candidates will receive regulatory approval once a BLA or similar application has been submitted. Obtaining approval of a BLA can be a lengthy, expensive, and uncertain process, and as a company we have no experience with the preparation and submission of a BLA 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 a REMS plan as part of a BLA approval or after BLA 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 may not be sufficient to support the submission of a BLA or other comparable foreign 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 product supply; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may change in a manner that renders 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.

The lengthy approval process, as well as the unpredictability of future clinical trial results, may prevent us from obtaining 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 in determining whether and when regulatory approval will be granted 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 for any of our product candidates, regulatory authorities may grant such approval for fewer or more limited indications than we request, may not approve the price we intend to charge for such product, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve such product with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product. 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 submission of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP and GCP regulations 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 approved product.

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 CDMOs will be subject to continual review and inspections to assess compliance with cGMP and cGTP regulations and adherence to commitments made in any approved marketing application. Accordingly, we and third parties that we engage or with which we conduct business 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 an approved product or our manufacture of such a product, or if we or one of our distributors, licensees, or co-marketers fails to comply with regulatory requirements, United States and foreign regulatory authorities could take various actions. These may include issuing warning letters or untitled letters, imposing fines on us, imposing restrictions on the applicable product or its manufacture, or requiring us to recall or remove the product from the market. Regulatory authorities could also suspend or withdraw our marketing authorizations, which could require us to conduct additional clinical trials, change our product labeling, or submit additional applications for marketing authorization. If any of these events were to occur, 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 obtain approval for any of our product candidates, 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 way, 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 be 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 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 requiring us to close our and our CDMOs’ 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 be subject to enforcement action 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 may 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, including personnel with the expertise necessary to evaluate product candidates such as ours, 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. Moreover, these and other factors have increased the uncertainties associated with interpreting the FDA’s guidance and predicting its areas of focus and responses to various issues. 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 extend the time necessary for new biologics or modifications to licensed biologics to be reviewed or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the United States 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 ongoing COVID-19 pandemic, in March 2020, the FDA temporarily postponed routine surveillance inspections of domestic and foreign manufacturing facilities. Subsequently, in July 2020, the FDA resumed certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA utilized this risk-based assessment system to assist in determining when and where it was safest to conduct prioritized domestic inspections. Additionally, on April 15, 2021, the FDA began conducting voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites, among other facilities, in circumstances where the FDA determines that such remote evaluation would be appropriate based on mission needs and travel limitations. In July 2021, the FDA resumed standard inspectional operations of domestic facilities. Since that time, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 pandemic. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the ongoing 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 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 may 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 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 and state governments and by 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 United States 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. 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 United States federal civil and criminal false claims laws, including the civil False Claims Act, which can be enforced by private citizens on behalf of the United States 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 United States 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 United States federal government. Pharmaceutical manufacturers can cause false claims to be presented to the United States 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 Federal Food, Drug, and Cosmetic Act (FDCA), which prohibits, among other things, the adulteration or misbranding of drugs, biologics, and medical devices;
- the United States 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 United States Physician Payments Sunshine Act (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 (CMS) information related to certain payments and other transfers of value to physicians, as defined by statute, certain non-physician practitioners (including physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants, and certified nurse-midwives), and teaching hospitals, as well as ownership and investment interests held by such physicians and their immediate family members;

- analogous United States state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including 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 United States 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. We have entered into consulting and scientific and clinical 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 and 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 and third parties that we engage or with which we collaborate in the course of our operations. It is not always possible to identify and deter misconduct or business noncompliance by our employees, consultants, and other agents, and we cannot ensure that precautions we take to detect and prevent inappropriate conduct, including our compliance controls, policies, and procedures, will in every instance protect us or be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming 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 employment, foreign corrupt practices, trade restrictions and sanctions, environmental, competition, and patient privacy and other data privacy and protection 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, report financial information or data accurately, comply with federal and state healthcare fraud and abuse laws and regulations, including prohibitions on pricing, discounting, labeling, marketing and promotion, sales commission, customer incentive programs, and other business arrangements, or disclose unauthorized activities to us. 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 comply with such laws or regulations.

If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material adverse effect on our business, financial condition, results of operations, and prospects. For example, we may be subject to or experience 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 charge for such product candidates.***

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 United States 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 (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 drugs, and a 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 that are inhaled, infused, instilled, implanted, or injected, which would include our product candidates;
- 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 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 under the 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, executive, 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. On June 17, 2021, the United States Supreme Court dismissed the most recent judicial challenge to the ACA without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order initiating a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted, including those which, among other things, have reduced Medicare payments available 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 target customers for our product candidates and accordingly, our financial operations. Moreover, payment methodologies may be subject to changes as a result of new 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.

Further, there have been a number of, and there may in the future be, other policy, legislative, and regulatory proposals aimed at changing the pharmaceutical industry. The United States government, state legislatures, and foreign governmental entities have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and coverage, and requirements for substitution of generic products for branded prescription drugs. Adoption of government controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could exclude or limit our product candidates from coverage and limit payments for pharmaceuticals. Most recently, on August 16, 2022, the Inflation Reduction Act of 2022 (IRA) was signed into law. Among other things, the IRA requires, beginning in 2026, that manufacturers of certain drugs engage in price negotiations with Medicare, with prices that can be negotiated subject to a cap; imposes rebates, first due in 2023, under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation; and, beginning in 2025, replaces the Part D coverage gap discount program with a new discounting program. The IRA permits the Secretary of the Department of Health and Human Services to implement many of these provisions through guidance, as opposed to regulation, for the initial years. For that and other reasons, it is currently unclear how the IRA will be effectuated.

In addition, under the accelerated approval provisions of the FDCA and the implementing regulations of the FDA, the FDA may, under certain circumstances, grant accelerated approval to a product designed to treat a serious condition and fill an unmet need, provided that, in most cases, the applicant agrees to conduct additional post-marketing clinical trials to verify and describe the product's clinical benefit. Failure to conduct such studies, or failure of such studies to confirm the product's clinical benefit, may result in FDA withdrawal of such approval. In response to certain concerns regarding the current accelerated approval pathway, Congress has considered and may in the future consider legislation that could change aspects of the accelerated approval pathway. While we cannot predict which, if any, changes Congress will include in such legislation, when such changes will be adopted, or how such changes will affect our business, any such changes could negatively impact our ability to obtain accelerated approval for our product candidates or increase the burden of compliance with post-marketing requirements, which could increase our costs and harm our ability to commercialize our products and obtain and maintain profitability.

Moreover, currently enacted legislation may not be renewed once it expires, which may make it more difficult for us to obtain regulatory approval for and commercialize our product candidates. For example, the Prescription Drug User Fee Act (PDUFA) was enacted by Congress in 1992 to allow the FDA to collect fees from parties that produce certain human drug and biological products. Among other things, the fees collected under PDUFA provide for the timely review of regulatory submissions, such as BLAs. PDUFA has been renewed multiple times since its enactment, including at the end of September 2022, which will allow the FDA to continue collecting prescription drug user fees in future fiscal quarters. However, there is no guarantee that future renewals will occur in a timely manner, if at all. In addition, there may be amendments to PDUFA that could significantly affect how regulatory submissions are reviewed, and we cannot predict the extent of such amendments and how they will affect our business. If PDUFA is not renewed or its renewal is delayed, or if PDUFA is amended in certain ways, the FDA's ability to review any regulatory submissions and related correspondence for our product candidates may be materially adversely impacted, which could negatively impact our development timelines and ability to obtain regulatory approval of our product candidates.

It is also possible that additional governmental action will be taken in response to address the ongoing 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 or with which we collaborate 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 be unable to obtain regulatory approval or 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 product candidates 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 that reimburse patients or healthcare providers are requiring that drug companies provide these payors 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 adversely affected.

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 product for which we receive regulatory approval will be reimbursed in all cases or at a rate that covers our costs, including for research, development, manufacture, sale, and distribution.

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

Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Third-party payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. As a result, the coverage determination process is often time-consuming and costly and will likely 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 what initiatives may be adopted in the future, including repeal or replacement of, or significant revisions to, the ACA. The continuing efforts of the government, insurance companies, managed care organizations, and other payors of healthcare services to contain or reduce costs of healthcare or impose price controls may adversely affect:

- the demand for any of our product candidates that may receive regulatory approval;
- our ability to set a price that we believe is fair for our approved products;
- our ability to obtain coverage and reimbursement approval for an approved 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 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 may obtain from research institutions participating in our clinical trials and directly from individuals.***

We and our partners and vendors are subject to various federal, state, and foreign data protection and privacy 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 potential loss of business.

In the United States, our and our partners' and vendors' operations are subject to 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. 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, failure 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 may contain sensitive identifiable personal information regarding the donor. In addition, once we commence clinical trials, we or our partners or vendors may maintain or otherwise have access to 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 may enroll in our patient assistance programs. We may become subject to further obligations under HIPAA as a result of our access to such information. In addition, our collection of personal information generally, including information of our employees or future patients, may subject us to state data privacy laws governing the processing of personal information and requiring notification to affected individuals and state regulators in the event of a data breach involving such personal information. These state laws include the California Consumer Privacy Act (CCPA) and its related regulations, and, effective January 1, 2023, the recently approved California Privacy Rights Act (CPRA) amending the CCPA, which establish data privacy rights for residents of the State of California, with corresponding obligations on businesses related to transparency, deletion, 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.

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 relating to data privacy and security has been proposed or enacted in various other states and at the federal level. Such legislation 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 and have potentially conflicting requirements that would make compliance challenging, require us to expend significant resources achieve compliance, and restrict our ability to process certain personal information.

Any clinical trial programs and research collaborations that we engage in outside the United States may implicate international data protection laws, including, in the European Union, the General Data Protection Regulation (GDPR). The GDPR imposes obligations in relation to the collection, processing, sharing, disclosure, transfer, and other use of data relating to an identifiable living individual, or "personal data," including a principle of accountability and the obligation to demonstrate compliance through policies, procedures, training, and audit. The GDPR imposes stringent operational requirements for data controllers and data processors of personal data. Among other things, the GDPR requires that detailed notices be provided to clinical trial subjects and investigators, as well as maintenance of certain security levels for personal data and notification of data breaches 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 must comply with both the GDPR and the GDPR as incorporated into United Kingdom national law (UK GDPR) with respect to any clinical trial data generated from the European Union and the United Kingdom, respectively, which may have differing requirements. We may be subject to diverging requirements under European Union member state laws and United

Kingdom law, such as whether consent can be used as the legal basis for processing of clinical trial data and the roles, responsibilities, and liabilities and respective data protection obligations as between CROs, clinical trial sites, and sponsors. As these laws develop, we may need to make operational changes to adapt to these diverging rules, which could increase our costs and adversely affect our business.

The GDPR and UK GDPR regulate cross-border transfers of personal data out of the European Economic Area (EEA) and the United Kingdom, respectively. Recent legal developments in Europe have created complexity and uncertainty regarding the legality of and requirements with respect to transfers of personal data from the EEA and United Kingdom to the United States and other countries in which we or our partners or service providers may operate. For example, on July 16, 2020, the Court of Justice of the European Union (CJEU) invalidated the EU-US Privacy Shield Framework (Privacy Shield), under which personal data could previously be transferred from the EEA and United Kingdom to United States entities that had self-certified under the Privacy Shield scheme. The CJEU decision also created additional obligations and uncertainty regarding the use of standard contractual clauses for such data transfers. Subsequent European court and regulator decisions have taken a restrictive approach to international 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 be subject to additional costs, complaints, regulatory investigations, or fines. If we are unable to transfer personal data between and among countries and regions in which we or our partners or vendors operate, it could adversely affect the manner in which we operate our business, affect the geographical location or segregation of our relevant systems and operations, and adversely affect our financial results. These laws and regulations may also apply to vendors that store or otherwise process personal data on our behalf, such as information technology or other vendors. If our data privacy or security measures fail to comply with applicable data privacy laws, or if a vendor misuses data we have provided to it or fails to safeguard such data, or otherwise fails to comply with such laws, we may be subject to litigation, regulatory investigations, enforcement notices, or enforcement actions imposing fines or requiring us to change the way we use personal data, as well as negative publicity, reputational harm, and potential loss of business. Failure to comply with the GDPR could result in penalties for noncompliance. Since we may be subject to the supervision of relevant data protection authorities under both the GDPR and the UK GDPR, we could be fined under each of those regimes independently in respect of the same breach. Penalties for certain breaches are up to the greater of €20 million (£17.5 million) or 4% of our global annual turnover. In addition to fines, failure to comply with the GDPR may result in regulatory investigations, reputational damage, orders to cease or change our data processing activities, enforcement notices, assessment notices for a compulsory audit, or civil claims, including class actions.

We expect that we will need 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 related to data privacy and security, even if we are not found liable, could be expensive and time-consuming to defend and could result in negative 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 and changes thereto, we could be subject to a range of regulatory actions that could affect our or any collaborators' ability to seek to commercialize our product candidates. Any threatened or actual government enforcement action, or litigation when private rights of action are available, could also generate negative 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 support of other aspects of our business.

### **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 \$189.0 million and \$245.2 million for the nine months ended September 30, 2022 and 2021, respectively. As of September 30, 2022, we had an accumulated deficit of \$974.4 million, which includes cumulative non-cash charges related to the revaluation of our success payment liabilities and contingent consideration of \$33.3 million and \$89.9 million, respectively. Our losses have resulted principally from expenses incurred for the research and development of our *ex vivo* and *in vivo* cell engineering platforms, management and administrative costs, and other expenses incurred while building our business infrastructure.



We expect our operating losses and expenses will continue to increase substantially for the foreseeable future, including as we:

- expand our research and development efforts;
- advance and expand the capabilities of our *ex vivo* and *in vivo* cell engineering platforms;
- identify additional product candidates;
- advance preclinical development of our current product candidates and initiate additional preclinical studies, including with respect to future product candidates;
- commence and advance through clinical studies of our current and future product candidates;
- establish our manufacturing capability, including developing our CDMO relationships and building our internal manufacturing facilities;
- acquire and license technologies aligned with our *ex vivo* and *in vivo* cell engineering platforms;
- seek regulatory approval of our current and future product candidates;
- engage in commercialization activities, including product manufacturing, marketing, sales, and distribution for any of our product candidates for which we obtain marketing approval;
- expand our operational, financial, and management systems and increase personnel, including those required to support our preclinical and clinical development, manufacturing, and potential future commercialization efforts;
- continue to develop, prosecute, and defend our intellectual property portfolio; and
- incur additional legal, accounting, and other expenses necessary to operate our business, including the 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 *ex vivo* and *in vivo* cell engineering platforms, identifying and developing potential product candidates, executing preclinical studies, establishing manufacturing capabilities, acquiring technology, organizing and staffing the company, developing and executing our business plan, 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, obtaining 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 biopharmaceutical product 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. As described above, our operations have consumed substantial amounts of cash since inception, and we expect our expenses to increase in connection with our ongoing activities. 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, 2022, we had \$511.6 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, 2022 will be sufficient to fund our operating expenses and capital expenditure requirements for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources more quickly than we currently expect, which could require us to seek additional funds sooner than planned, including 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. For example, in August 2022, we entered a sales agreement with Cowen, acting as sales agent, pursuant to which we may offer and sell through Cowen shares of our common stock having an aggregate offering price of up to \$150.0 million from time to time in a series of one or more at the market equity offerings (collectively, the ATM facility). As of September 30, 2022, we had raised approximately \$0.7 million in net proceeds under the ATM facility. 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 and scope of clinical trials required for regulatory approval of our current or future product candidates;
- the costs, timing, and outcome of regulatory review 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;
- the expenses required 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 payors;
- potential interruptions or delays resulting from factors related to the ongoing 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 ongoing COVID-19 pandemic or other factors, such as the recent escalation in conflict between Russia and Ukraine, 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 and at a cost 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 or establish and operationalize our manufacturing facility, establish sales and marketing capabilities, or other activities that may be necessary to commercialize any product candidates for which we obtain regulatory approval, or reduce our flexibility in developing or maintaining our sales and marketing strategy with respect to any product candidates for which we obtain regulatory approval.

***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 received under any future licenses or collaborations. Additional capital may not be available on reasonable terms, if at all. If we raise additional capital through the sale of equity or debt securities, existing stockholders' ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our stockholders. 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.

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

We agreed to make success payments, payable in cash, pursuant to our license agreement with Harvard and contingent consideration and success payments, payable in cash or stock, pursuant to our acquisition agreement with 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 maximum amount would only be payable 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 that 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 Harvard 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. As of September 30, 2022, a Harvard Success Payment had not been triggered. See Note 4, License and collaboration agreements to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report for more details on the per share common stock values that trigger a Harvard Success Payment.

In connection with the Cobalt acquisition, we are obligated 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 stockholders (Cobalt Success Payment) of \$500.0 million if, at pre-determined valuation measurement dates, which include the closing of 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 BLA or new drug application. 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. As of September 30, 2022, a Cobalt Success Payment had not been triggered. See Note 3, Acquisitions, to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report for details on the amount of the potential Cobalt Success Payment and potential Cobalt Contingent Consideration if there is a change of control based on various thresholds for our market capitalization on such change of control date.

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 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.

***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 United States generally accepted accounting principles 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 balance sheets. Under United States generally accepted accounting principles (GAAP), we are required to estimate the fair value of these liabilities as of each quarter end, with changes in the estimated fair value recorded in research and development-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, 2022 and December 31, 2021, the estimated aggregate fair value of the Cobalt Success Payment and Harvard Success Payment liabilities was \$35.7 million and \$102.5 million, respectively, and the estimated fair value of the Cobalt Contingent Consideration was \$141.1 million and \$153.7 million, respectively.

For the three months ended September 30, 2022, we recorded a gain of \$0.2 million related to the change in the estimated fair value of the Harvard Success Payments. For the three months ended September 30, 2022, we recorded an expense of \$2.4 million related to the change in the estimated fair value of the Cobalt Success Payment. For the Harvard Success Payments, keeping all other variables constant, a hypothetical 20% increase in our common stock price at September 30, 2022 from \$6.00 per share to \$7.20 per share would have decreased the gain recorded in the three months ended September 30, 2022 associated with the success payment liability to zero, resulting in an expense of \$1.0 million. A hypothetical 20% decrease in the common stock price from \$6.00 per share to \$4.80 per share would have increased the gain recorded in three months ended September 30, 2022 by \$1.1 million to \$1.3 million.

For the Cobalt Success Payment, keeping all other variables constant, a hypothetical 20% increase in our market capitalization at September 30, 2022 from \$1.1 billion to \$1.4 billion would have increased the expense recorded in the three months ended September 30, 2022 associated with the success payment liability by \$8.6 million to \$11.0 million. A hypothetical 20% decrease in our market capitalization from \$1.1 billion to \$0.9 billion would have decreased the expense recorded in the three months ended September 30, 2022 to zero, resulting in a gain of \$5.6 million.

We have incurred net losses since our inception and expect to continue to incur net losses for the foreseeable future. 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 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 to evaluate our prospects and likelihood of success.***

We are a preclinical-stage biopharmaceutical company with a limited operating history upon which to 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 *ex vivo* and *in vivo* cell engineering platforms, identifying and developing potential product candidates, executing preclinical studies, establishing manufacturing capabilities, acquiring technology, organizing and staffing the company, developing and executing our business plan, 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, predictions about our future success or viability are difficult to make and may not be as accurate as they could be if we had a longer operating history.

## 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 companies, 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 pharmaceutical and biotechnology industries may result in even more resources, including intellectual property that may be necessary or useful for the development and commercialization of our product candidates, being concentrated in our competitors and becoming unavailable to us on reasonable commercial terms or at all. 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, and as new technologies become available, we expect to face increasingly intense competition. 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 technologies 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 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, our collaborators may decide to market and sell products that compete with the product candidates that we have agreed to license to them, which could 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. We currently and in the future will compete with these third parties in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites, and recruiting patients for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. See the subsection titled “Business—Competition” in the 2021 Annual Report.

***Market opportunity and market growth for our product candidates may prove to be smaller than we initially 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 therapies that enter the market. If any of our estimates proves to be inaccurate, the market opportunity for any product candidate that we or our strategic partners develop could be significantly diminished, which would 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 beyond, 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, which usually consists of 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 certain classes of therapies, including CAR T therapies, has been limited to a subset of patients with relapsed or refractory disease. 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. Each of these commercialization strategies carries substantial risks to us.***

We currently have no marketing, sales, or distribution capabilities because all of our product candidates are still in preclinical development. If one or more of our product candidates complete clinical development and receive regulatory approval, 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 functions. 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 subject us 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 ability to complete our obligations under these 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 products for which we receive regulatory approval. If we are not successful in commercializing any approved products, either on our own or through collaborations with one or more third parties, our ability to generate 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 the competing 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 therapy products that 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 that may be 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 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 outside the United States have also 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, we are not currently able to predict with certainty the length of market exclusivity for any particular product candidate that may receive marketing approval based solely on the expiration of the relevant patent(s) or the current forms of regulatory exclusivity. There may also be future changes in United States regulatory law that might reduce biological product regulatory exclusivity. The loss of market exclusivity for any product for which we receive regulatory approval could materially and negatively affect our ability to generate revenues, which could prevent us from generating adequate or sufficient revenues and being able to achieve or sustain profitability.

### **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, 2022, our executive officers, directors, holders of 5% or more of our capital stock, and their respective affiliates, owned approximately 64.2% 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 other stockholders may feel are in their best interests.

***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, 2022, 189.9 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. Additionally, as of September 30, 2022, we had raised approximately \$0.7 million in net proceeds under the ATM facility. All shares of common stock sold in the ATM facility are freely tradable without restriction or further registration under the Securities Act, unless held by our "affiliates" as defined in Rule 144 under the Securities Act. 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. We also register the offer and sale of all shares of common stock that we may issue under our equity compensation plans. Accordingly, these shares may 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 of 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 are 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 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
- limit 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 will 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 (Tax Act), 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 Act 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 NOL 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 and gain the benefit of a material portion of our NOLs and tax credits.

**General Risk Factors**

***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 future clinical trials;
- changes or fluctuations in our stock price and market capitalization, which could impact the value of our contingent obligations and cause fluctuations in our operating expenses as a result of these non-cash adjustments;
- impacts from the ongoing COVID-19 pandemic on us or third parties with which we collaborate or that we engage;
- results of future clinical trials, or the addition or termination of such clinical trials or funding support by us or potential future partners or other third parties;
- our execution of any collaboration, licensing, or similar arrangements, and the timing of payments we may make or receive under such arrangements or the termination or modification of any such arrangements;
- any intellectual property infringement, misappropriation, or violation lawsuit or opposition, interference, post-grant proceeding, 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;
- the impact of global supply chain issues and rising rates of inflation on the costs of laboratory consumables, supplies, and equipment required for our ongoing operations;
- 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 candidate;
- the timing and cost of establishing 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.

***Our stock price may be volatile or may decline regardless of our operating performance, which may result in substantial losses for investors and may potentially subject us to securities class action litigation, which is expensive and could divert management's attention.***

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, and many of which are beyond our control, including the factors listed below and other factors describe in these Risk Factors:

- the commencement of, enrollment in, or results of current and future preclinical studies and clinical trials we may conduct, or changes in the development status of our product candidates;
- any delay in 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 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 preclinical study or clinical trial requirements for regulatory approvals worldwide;
- adverse changes to our relationship with manufacturers or suppliers;
- manufacturing, supply, or distribution shortages;
- our failure to successfully 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 patent rights, trade secrets, litigation matters, and our ability to obtain patent protection for our technologies or product candidates;
- 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 *ex vivo* and *in 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 both within and outside the United States, including geo-political and economic instability resulting from the recent escalation in conflict between Russia and Ukraine and economic and tax policies announced by foreign countries; 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.

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. The market price of our common stock has fluctuated since our IPO and may continue in the future to be volatile. 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.

***Market and economic conditions may negatively impact our business, financial condition, and share price.***

Concerns about inflation, energy costs, geo-political issues, the United States mortgage market and a declining real estate market, unstable global credit markets and financial conditions, and volatile oil prices have led to periods of significant economic instability, diminished liquidity and credit availability, declines in consumer confidence and discretionary spending, diminished expectations for the global economy and expectations of slower global economic growth going forward, increased unemployment rates, and increased credit defaults in recent years. Our general business strategy may be adversely affected by any such economic downturns, volatile business environments and continued unstable or unpredictable economic and market conditions. For example, given the volatility in our stock price and the increased difficulty in accessing global credit markets due to the market and economic conditions described above, we have adjusted our pipeline prioritization strategy and resource allocation in order to enable the success of our most advanced product candidates. Accordingly, we may experience delays in developing and commercializing certain product candidates. In addition, if the market and economic conditions described above continue to deteriorate or do not improve, it may make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance, and stock price. As a result, we may be required to further adjust our pipeline prioritization strategy and resource allocation in order to extend our cash runway and enable the success of certain of our product candidates, which may require us to slow or stop the development of other product candidates. Additionally, rising rates of inflation have increased the costs associated with conducting our business, including by causing substantial increases in the costs of materials, including raw materials and consumables, equipment, services, and labor. Given that we do not currently generate revenue from sales of any of our product candidates, we do not have an ability to offset these increases in our costs. Moreover, given the unpredictable nature of the current economic climate, including future changes in rates of inflation, it may be increasingly difficult for us to predict and control our future expenses, which may harm our ability to conduct our business.

***We or the third parties upon whom we depend may be adversely affected by natural disasters, including earthquakes, fires, typhoons, and floods, public health epidemics, such as the ongoing COVID-19 pandemic, telecommunications or electrical***

***failures, geo-political actions, including war and terrorism, political and economic instability, and other events beyond our control, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.***

We or our partners, CROs, CDMOs, or other service providers, may experience interruptions to our operations, including the conduct of our research and development programs, clinical trials, and manufacturing operations, due to natural disasters, including earthquakes, fires, typhoons, and floods, public health epidemics, such as the ongoing COVID-19 pandemic currently impacting countries worldwide, hardware, software, telecommunication or electrical failures, geo-political actions, including war and terrorism, or political and economic instability, which could significantly disrupt or harm our business.

Our corporate headquarters and other facilities, including the 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, electrical failure, or other event occurs that prevents us from using all or a significant portion of our headquarters, damages critical infrastructure, or otherwise disrupts operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. For example, a prolonged electrical failure could result in damage to or destruction of materials that are critical for our research and manufacturing operations, including our master cell banks, which would delay the advancement of our programs and materially harm our business, operating results, prospects, or financial condition. In addition, a failure of our computing systems could result in the loss of research or preclinical data important to our research or development programs, interrupt the conduct of ongoing research, or otherwise impair our ability to operate, which could delay the advancement of our programs or cause us to incur costs to recover or reproduce lost data. 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 manufacture sufficient supply of our product candidates required to conduct our clinical trials or commercialize our products in accordance with our timelines or at all. The disaster recovery and business continuity plans we currently have in place 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, together with our lack of earthquake insurance in particular, could have a material adverse effect on our business.

Integral parties in our supply chain are similarly vulnerable to natural disasters or other sudden, unforeseen, and severe adverse events. In addition, our supply chain is vulnerable to changes in the geo-political and economic climate, including changes in relationships between the United States and countries from which we may need to source materials and other resources necessary for the preclinical evaluation of our product candidates, including animal models, and specifically non-human primate models, or to manufacture our product candidates, including raw and intermediate materials and consumables. If any such event or change were to affect our supply chain, it could have a material adverse effect on our business.

Furthermore, geo-political actions, and the resulting political and economic instability, could negatively impact our operations. For example, in late February 2022, Russia initiated significant military action against Ukraine. In response, the United States and certain other countries imposed significant sanctions and trade actions against Russia and could impose further sanctions, trade restrictions, and other retaliatory actions if the conflict continues or worsens. It is not possible to predict the broader consequences of the conflict, including related geo-political tensions, and the measures and retaliatory actions that will be taken by the United States and other countries in respect thereof, as well as any countermeasures or retaliatory actions Russia may take in response, are likely to cause regional instability and geo-political shifts and could materially adversely affect global trade, currency exchange rates, regional economies, and the global economy. While it is difficult to anticipate the impact of any of the foregoing on our company in particular, the conflict and actions taken in response to the conflict could increase our costs, disrupt our supply chain, impair our ability to raise or access additional capital when needed on acceptable terms, if at all, or otherwise adversely affect our business, financial condition, and results of operations.

***We are subject to United States 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 could face criminal liability and other serious consequences for violations, which would harm our business.***

We are subject to export control and import laws and regulations, including the United States Export Administration Regulations, United States Customs regulations, various economic and trade sanctions regulations administered by the United States Treasury Department's Office of Foreign Assets Controls, the United States Foreign Corrupt Practices Act of 1977, as amended (FCPA), the United States domestic bribery statute contained in 18 U.S.C. § 201, the United States 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 any products for which we receive regulatory approval 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 United Kingdom or European Union, result in restrictions or imposition of taxes and duties for importing our product candidates into the United Kingdom or European Union, and may require us to incur additional expenses in order to develop, manufacture, and commercialize our product candidates in the United Kingdom or European Union.***

Following the result of a referendum in 2016, the United Kingdom (UK) left the European Union (EU) on January 31, 2020, commonly referred to as “Brexit.” Pursuant to the formal withdrawal arrangements agreed between the UK and the EU, the UK was subject to a transition period until December 31, 2020 (the Transition Period), during which time EU rules continued to apply. Negotiations between the UK and the EU continue in relation to the customs and trading relationship between the UK and the EU following the expiry of the Transition Period. The transition period provided time for the UK and EU to negotiate a framework for partnership for the future, which was ultimately crystallized in the Trade and Cooperation Agreement (TCA) and became effective on January 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, including the mutual recognition of GMP inspections of manufacturing facilities for medicinal products and GMP documents issued, but does not foresee wholesale mutual recognition of UK and EU pharmaceutical regulations.

Since a significant proportion of the regulatory framework in the UK 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 UK or the EU. For example, following the referendum, as required by EU law, the EMA relocated to Amsterdam from London. As of January 1, 2021, the Medicines and Healthcare Products Regulatory Agency (MHRA) is the UK’s standalone medicines and medical devices regulator. As a result of the Northern Ireland protocol, different rules apply in Northern Ireland than in Great Britain; broadly, Northern Ireland continues to follow the EU regulatory regime, but its national competent authority remains the MHRA. The MHRA has published guidance on how various aspects of the UK regulatory regime for medicines will operate in Great Britain and in Northern Ireland following the expiry of the Transition Period. The guidance addresses clinical trials, importing, exporting, and pharmacovigilance and is relevant to any business involved in the research, development, or commercialization of medicines in the UK. Following the Transition Period, the UK is no longer covered by the centralized procedures for obtaining EU-wide marketing authorization from the EMA and companies established in the UK must follow one of the UK national authorization procedures or one of the remaining post-Brexit international cooperation procedures to obtain marketing authorization to commercialize a product in the UK. The MHRA may rely on a decision taken by the European Commission with respect to the approval of a new (centralized procedure) marketing authorization when making a determination with respect to an application for a Great Britain marketing authorization, or use the MHRA’s decentralized or mutual recognition procedures, which enable marketing authorizations approved in EU member states (or Iceland, Liechtenstein, or Norway) to be granted in Great Britain. 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 UK or the EU 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 EU, or we may incur expenses in establishing a manufacturing facility in the EU 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 UK or the EU 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. 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 UK.

***If securities or industry analysts either do not publish research about us or publish inaccurate or unfavorable research about us, our business, our market, or our competitors, 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 is 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 such coverage or fail to regularly publish reports on us, we could lose visibility in the financial markets, which 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 reports 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 \$1.235 billion in annual revenue;
- the date we qualify as a “large accelerated filer,” with at least \$700 million of equity securities held by non-affiliates;
- the date on which we have issued, in any three-year period, more than \$1.0 billion in non-convertible debt securities; or
- the last day of the fiscal year ending after the fifth anniversary of the completion of our initial public offering, which is December 31, 2026.

We cannot predict if investors will find our common stock less attractive as a result of our decision 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 opted out of the extended transition period); however, we may adopt certain new or revised accounting standards early. As a result, these financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

***The requirements of being a public company may strain our resources, result in an increased risk of 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 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 the requirements of the Sarbanes-Oxley Act, 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 continue 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 potential revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations, and standards fail to meet the requirements of the applicable regulatory or governing bodies due to ambiguities related to their application in 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. Additionally, the dramatic increase in the cost of such insurance may cause us to opt for lower overall policy limits or to forgo insurance that we may otherwise rely on to cover defense costs, settlements, and damages awarded to plaintiffs in connection with any securities litigation.

By disclosing information in the periodic filings required of a public company, our business and financial condition are 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 is required to report upon the effectiveness of our internal control over financial reporting. 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, and procedures, and hire additional accounting and finance staff.

We cannot guarantee 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 with a related party, which could cause 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**

We did not sell any unregistered securities in the three months ended September 30, 2022.

**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. We hold a significant portion of the balance of the net proceeds from the offering in money market funds and short-term investments in accordance with our investment policy. There has been no material change in the planned use of proceeds from the IPO from that described in the prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on February 3, 2021.

**Item 3. Defaults Upon Senior Securities**

Not applicable.

**Item 4. Mine Safety Disclosures**

Not applicable.

**Item 5. Other Information**

(a)

Not applicable.

(b)

Not applicable.



## Item 6. Exhibits

Exhibit Number	Description
3.1	<a href="#">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).</a>
3.2	<a href="#">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).</a>
4.1	Reference is made to Exhibits <a href="#">3.1</a> through <a href="#">3.2</a> .
4.2	<a href="#">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).</a>
10.1*†	<a href="#">Amendment No. 2 to Patents Sub-License Agreement by and between the Company and La Societe Pulsalys, dated as of March 9, 2022.</a>
10.2*†	<a href="#">Amendment No. 2 to Option and License Agreement by and between the Company and Beam Therapeutics Inc., dated as of July 19, 2022.</a>
10.3*†	<a href="#">Amendment No. 5 to Exclusive Start-Up License Agreement by and between the Company and University of Washington (UW), dated as of February 25, 2021.</a>
10.4*†	<a href="#">Amendment No. 6 to Exclusive Start-Up License Agreement by and between the Company and UW, dated as of March 11, 2021.</a>
10.5*†	<a href="#">Amendment No. 7 to Exclusive Start-Up License Agreement by and between the Company and UW, dated as of April 14, 2021.</a>
10.6*†	<a href="#">Amendment No. 8 to Exclusive Start-Up License Agreement by and between the Company and UW, dated as of July 20, 2021.</a>
10.7*†	<a href="#">Amendment No. 9 to Exclusive Start-Up License Agreement by and between the Company and UW, dated as of September 9, 2021.</a>
10.8*†	<a href="#">Amendment No. 10 to Exclusive Start-Up License Agreement by and between the Company and UW, dated as of October 30, 2021.</a>
10.9*†	<a href="#">Amendment No. 11 to Exclusive Start-Up License Agreement by and between the Company and UW, dated as of July 14, 2022.</a>
10.10*#	<a href="#">Offer Letter and Employment Agreement by and between the Company and Bernard Cassidy, dated as of September 8, 2022.</a>
10.11*#	<a href="#">Amendment No. 1 to the 2021 Employee Stock Purchase Plan, dated as of October 27, 2022.</a>
31.1*+	<a href="#">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.</a>
31.2*+	<a href="#">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.</a>
32.1*+	<a href="#">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.</a>
32.2*+	<a href="#">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.</a>
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.

# Indicates management contract or compensatory plan.

† Certain portions of this document that constitute confidential information have been redacted in accordance with Regulation S-K, Item 601(b)(10).

+ These certifications are not deemed filed with the Securities and Exchange Commission and are 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, irrespective of any general incorporation language contained in such filing.



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

### AMENDMENT NO. 2 TO PATENTS SUB-LICENSE AGREEMENT

This Amendment No. 2 to Patents Sub-License Agreement (“Amendment No. 2”), effective as of 16 August 2018 (“Amendment No. 2 Effective Date”), is entered into by and between LA SOCIETE PULSALYS, a company organized under French Law, having its registered office at [\*\*\*] (French company registration number) [\*\*\*], Code [\*\*\*] (French principal activity code) [\*\*\*] (“Pulsalys”) and Sana Biotechnology, Inc. a Delaware corporation having offices at 188 East Blaine St., Seattle WA, 98102 (“Sana”).

WHEREAS, Pulsalys and Cobalt Biomedicine, Inc. a Delaware corporation having offices at 188 East Blaine St., Seattle WA, 98102 (“Cobalt”), an Affiliate of Sana and predecessor in interest to Sana, entered into that certain Patents Sub-License Agreement dated August 16, 2018 (the “Original Agreement”);

WHEREAS, Pulsalys and Cobalt had previously entered into that certain Materials Transfer Agreement dated as of 13 July 2018 (the “MTA”) pursuant to which Pulsalys transferred to Cobalt certain biological or chemical materials as set forth in the MTA for use in an Evaluation (as defined in the MTA) by Cobalt;

WHEREAS, Sana acquired Cobalt effective as of February 14, 2019 pursuant to that certain Agreement and Plan of Merger by and between, *inter alia*, the Sana and Cobalt dated December 20, 2018, as amended, and Cobalt is a wholly-owned subsidiary of Sana;

WHEREAS, Cobalt assigned the Agreement, and all rights, obligations, and interest therein, to Sana, Pulsalys consented to such assignment, and Pulsalys and Sana amended the Agreement, pursuant to that certain Amendment No. 1 to Patents Sub-License Agreement dated as of 26 May 2020 (“Amendment No. 1”);

WHEREAS, Pulsalys and Sana now wish to further amend the Agreement, *nunc pro tunc*, effective as of the Amendment No. 2 Effective Date, to set forth and clarify Cobalt’s and Sana’s rights to continue to use the materials originally transferred by Pulsalys to Cobalt under the MTA.

WHEREAS, the parties wish to otherwise amend the Agreement as set forth herein.

In consideration of the covenants and conditions contained herein, the parties hereby agree to the following:

1. The term “Agreement” as used in this Amendment No. 2 and in the Original Agreement shall mean the Original Agreement as amended by Amendment No. 1 and Amendment No. 2. Except as otherwise set forth herein, capitalized terms used herein shall have the meaning set forth in the Original Agreement.
2. The term “MTA” as used in the Agreement shall mean the MTA as defined in this Amendment No. 2.
3. The following is hereby included in the Agreement as a new Section 1.5 of the Agreement:
  - a. “1.5 Notwithstanding anything to the contrary in the MTA, Pulsalys hereby grants Cobalt the non-exclusive right to use the Materials in connection with the exercise of the rights granted hereunder, including under Section 1.1, to research, make, use, have used, develop, produce, have produced, market, and sell Products, or products that were Products at any time (the “Permitted Use”). Cobalt shall use the Materials solely for the Permitted Use and in accordance with all applicable laws and regulations and for no other purpose. Sana shall retain control of Materials and, without the prior and express consent of Pulsalys, shall not sell, transfer, distribute or otherwise release the Materials to any third party except to sublicensees hereunder, or its or their contract research organizations, service providers, contract manufacturers or other entities performing research with or on behalf of Cobalt or their sublicensees (“Service Providers”), provided that Cobalt shall ensure that any such organizations or entities are subject to all requirements and obligations hereunder with respect to the use of the Materials and provided further that such organizations and entities shall not be permitted to further transfer, distribute or release the Materials to any third party. Cobalt will ensure that any of its employees and Service Providers having access to the Materials will use the Materials in a manner that is consistent with the terms of this Agreement. The parties hereby agree that, as of the Amendment No. 2 Effective Date, (a) the terms of this Section 1.5, Section 10.5 and Section 10.6 supersede all terms of the MTA (including, for clarity, Section 12.2 of the MTA) with respect to Cobalt’s use and/or transfer of the Materials hereunder, (b) all such terms shall be of no further force or effect and (c) any surviving terms of the MTA shall apply solely to the use of the Materials under the MTA in connection with the Evaluation and not to Cobalt’s use and/or transfer of the Materials hereunder. In addition, the parties agree that all rights and obligations of this Agreement with respect to the use and disclosure of Confidential Information shall apply with respect to “Confidential

Information” as defined in and as disclosed under the MTA and that the applicable terms of this Agreement supersede the terms of the MTA and control with respect to the use and or disclosure of such information.

4. The following is hereby included as Appendix 2 to the Agreement:

Appendix 2

[\*\*\*]

5. The following is hereby included in the Agreement as a new Section 10.5 of the Agreement:

- a. “10.5 Cobalt shall obtain all import licenses or needed authorization in order to import or export the Material. Cobalt undertakes to give to Pulsalys, before sending the Original Material, a written notification informing that the import license needed or any other required authorization with an identification number, or if no import license or authorization are needed a statement to this end. Pulsalys shall provide to Cobalt information regarding security, handling and regulatory requirements or other information regarding the Original Material to the extent that it is needed in order to respect applicable import and export laws in the framework of the delivery of the Original Material and applicable laws regarding the use, the storage, or the transport of the Original Material, or application for regulatory approval or maintenance of such approval of any Product.

6. The following is hereby included in the Agreement as a new Section 10.6 of the Agreement:

- b. “10.6 Cobalt acknowledges that the Original Material is provided “as is” without any guarantee regarding their usefulness or adaptation for any use. As the Material is of an experimental nature, no warranty is provided as regards its condition, activity, usefulness, efficiency, purity, harmlessness, non-toxicity, safety, or as regards its use, market value or suitability in respect of any and all objective. In particular, Pulsalys do not warrantee that the use of the Material will not infringe the intellectual property rights of any third party. Cobalt shall be solely liable for any and all rises or loss which may arise from the use of the Materials, in particular in the event of injury, death, physical damage, or any and all other incident or loss that may be occasioned by the acts or omissions linking to the Material or a Product expressed with its use thereof.

7. Miscellaneous

Except as expressly set forth herein, the terms and conditions of the Original Agreement shall remain in full force and effect. In the event of any conflict between the terms and conditions of this Amendment No. 2 and the Original Agreement, the terms and conditions set forth in this Amendment No. 2 shall control with respect to the subject matter hereof.

No provision of this Amendment No. 2 may be amended or otherwise modified except by a writing signed by the parties to this Amendment No. 2. The parties may execute this Amendment No. 2 by electronic signature in counterparts, each of which will be deemed an original, but all of which together constitute one and the same agreement. This Amendment No. 2 may be delivered by facsimile transmission or electronic mail, and such copies of executed signature pages will be binding as originals.

IN WITNESS WHEREOF, the parties by their duly authorized representatives have executed this Amendment No. 2 as of the Amendment No. 2 Effective Date.

**Sana Biotechnology, Inc.:**  
 09/03/2022  
 /s/ Jagesh SHAH  
 Name: M. Jagesh SHAH  
 Title: Vice President, Gene Therapy Technologies,  
 Of Sana Biotechnology, Inc.  
 Date:

**PULSALYS:**  
 07/03/2022  
 /s/ Sophie JULLIAN  
 Name: Ms. Sophie JULLIAN  
 Title: President of PULSALYS  
 Date:

**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**

**AMENDMENT NO. 2 TO OPTION AND LICENSE AGREEMENT**

This **Amendment No. 2 to Option and License Agreement** (the “**Second Amendment**”) is made as of July 19, 2022 (the “**Second Amendment Effective Date**”), by and between **Beam Therapeutics Inc.**, a Delaware corporation having an office at 238 Main Street, Cambridge, MA 02142 (“**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 Second Amendment individually as a “**Party**” and collectively as the “**Parties**”.

**RECITALS**

**WHEREAS**, the Parties have entered into that certain Option and License Agreement, dated October 15, 2021 (the “**Original Agreement**”), as amended by that certain Amendment No. 1 thereto dated June 6, 2022 (the “**First Amendment**”) (the Original Agreement as amended by the First Amendment, the “**Agreement**”) pursuant to which Sana obtained a non-exclusive license from Beam to use 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; and

**WHEREAS**, Sana desires to perform the [\*\*\*] study described in Attachment 1 of this Second Amendment (the “[\*\*\*] **Study**”) to support research and development of Licensed Products and, in connection with the [\*\*\*] Study desires to use Beam’s nuclease editing technology solely for [\*\*\*] using Beam’s technology, and Beam has agreed to grant Sana such right;

**WHEREAS**, the Parties wish to extend the Additional Selection Term under the Agreement by period of [\*\*\*] ([\*\*\*]) months; and

**WHEREAS**, the Parties now desire to amend the Agreement in accordance with Section 14.9 of the Agreement.

**NOW, THEREFORE**, the Parties now desire, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, to amend the Agreement as set forth in this Second Amendment.

**ARTICLE 1  
AMENDMENTS**

1.1 **Defined Terms.** Capitalized terms used herein but not otherwise defined shall have the meaning ascribed to such terms in the Agreement.

1.2 **Addition of Exhibits H and I.** The plan for performance of the [\*\*\*] Study set forth in Attachment 1 is hereby added to the Agreement as Exhibit H. The genetic target list set forth in Attachment 2 is hereby added to the Agreement as Exhibit I.

1.3 **Addition of Definitions.** The following definitions are hereby added to Article 1 of the Agreement:

1.23A “[\*\*\*] Study” means the study described in Exhibit H.

1.43A “**Development Product**” means the therapeutic product described in Exhibit H that is or contains a [\*\*\*] cell that has been Edited in the course of the [\*\*\*] Study, including any cell that is cultured or physically descended from any such Edited [\*\*\*] cell.

1.43B “**Development Product Term**” means the period commencing on the Second Amendment Effective Date, and ending on the earliest to occur of: (i) [\*\*\*]; (ii) receipt by Beam of written notice from Sana stating that Sana no longer desires to exercise its rights with respect to Development Products under this Agreement; or (iii) the date the last patient is dosed in the [\*\*\*] Study.

1.4 **Amendment of Definition.** The following definition is hereby deleted in their entirety and replaced with the following:

1.1 “**Additional Selection Term**” means the period starting on the Effective Date and ending on [\*\*\*].

1.5 **Addition of Section 2.1A.** The following is hereby added to the agreement as new Section 2.1A, immediately following existing Section 2.1:

2.1A **Limited License for [\*\*\*] Study.**

- (a) Beam hereby grants to Sana a non-exclusive, non-transferable license, without the right to grant sublicenses except as set forth in Section 2.1A(b) below, (i) under the Beam Platform Technology to: (1) manufacture and have manufactured the Cas12b Platform Components; and (2) use the Cas12b Platform Components to perform Nuclease Editing; and (ii) under the Beam Platform Technology and Beam Product Technology Patents to research and develop Development Products in the Territory solely through the [\*\*\*]; in each case of (i) and (ii) solely (x) during Development Product Term, and (y) for purposes of performing the [\*\*\*] Study in furtherance of researching and developing Licensed Products. For purposes of the license set forth in this Section 2.1A(a), the Genetic Targets will be limited to the targets listed in Exhibit I.
- (b) The license set forth in Section 2.1A(a) above is not sublicensable, except that Sana may grant sublicenses under such license (through [\*\*\*]) solely to Sana’s CROs, CMOs and Subcontractors solely for purposes of performing activities under the [\*\*\*] Study in furtherance of researching and developing Licensed Products. If Sana grants a sublicense under Section 2.1A(a) as permitted in the foregoing sentence: (i) Sana shall remain responsible for the performance of such CMOs, CROs and

Subcontractors to the same extent as if such activities were conducted by Sana; and (ii) Sana will insure that the applicable agreement includes (A) the requirement that such CRO, CMO or Subcontractor complies with the provisions set forth on Exhibit D, and (B) all other provisions set forth in Section 2.4 of the [\*\*\*] Agreement, as applicable to such CRO, CMO or Subcontractor.

- (c) Sections 6.1, 6.2, 6.3, 6.4, 6.5, 8.6, 10.4, 10.5, 11.3, 12.4(b), 13.2, 13.6, 14.1, 14.10 and Exhibit D of the Agreement, and the defined terms therein, shall apply *mutatis mutandis* with respect to the Development Products as if they were Licensed Products thereunder; provided, however, that nothing in the above-described sections will be deemed to permit Sana to perform any activities with respect to Development Products other than performance of the [\*\*\*] Study.
- (d) Except as set forth in Section 8.6 of the Agreement, no milestone payment is owed by Sana to Beam pursuant to Section 8.4 of the Agreement in connection with Sana's research and development of the Development Products or the exercise of the license set forth in Section 2.1A(a).

## ARTICLE 2 MISCELLANEOUS

2.1 **Counterparts.** This Second Amendment may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Each Party may rely on the delivery of executed electronic copies of counterpart execution pages of this Second Amendment and such electronic copies shall be legally effective to create a valid and binding agreement among the Parties.

2.2 **Scope.** This Second Amendment supersedes all proposals, negotiations, conversations and/or discussions between or among parties relating to the subject matter of this Second Amendment and all past dealing or industry custom. This Second Amendment shall be integrated in and form part of the Agreement effective as of the Second Amendment Effective Date. Except for the foregoing modifications, the Agreement is hereby ratified and confirmed in accordance with its the terms thereof.

*[Remainder of Page Intentionally Left Blank]*



**IN WITNESS WHEREOF**, the Parties intending to be bound have caused this Amendment No. 2 to Option and License Agreement to be executed by their duly authorized representatives as of the Second Amendment Effective Date.

**Beam Therapeutics Inc.**

By: /s/ John Evans  
Name: John Evans  
Title: CEO

**Sana Biotechnology, Inc.**

By: /s/ Christian Hordo  
Name: Christian Hordo  
Title: Chief Business Officer

[Signature Page to Amendment No. 2 to Option and License Agreement]

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**Attachment 1**

**Exhibit H**

**[\*\*\*] Study**

**[\*\*\*]**

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**Attachment 2**

**Exhibit I**

**Genetic Target List**

[\*\*\*]

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

AMENDMENT NO. 5 TO  
EXCLUSIVE START-UP LICENSE AGREEMENT BETWEEN  
SANA BIOTECHNOLOGY, INC. AND UNIVERSITY OF WASHINGTON

THIS AMENDMENT NO. 5 ("Amendment No. 5"), with an effective date of as of the date of the last signature ("Amendment No. 5 Effective Date"), is entered into by and between Sana Biotechnology, Inc. ("Company") and University of Washington ("University").

WHEREAS, Cytocardia, Inc. ("Cytocardia") and University entered into an Exclusive Start-Up License Agreement for [\*\*\*], with a University Reference [\*\*\*], dated October 9, 2018 (the "Original Agreement"), and amended on November 6, 2019 ("Amendment No. 1"), and July 16, 2020 ("Amendment No. 2");

WHEREAS, Cytocardia assigned the Original Agreement, as amended by Amendment No. 1 and Amendment No. 2, to Company pursuant to that certain Assignment of License Agreement dated as of effective as of November 11, 2020, and pursuant to which Assignment of License Agreement the parties thereto further amended the Original Agreement, as amended by Amendment No.1 and Amendment No. 2 thereto ("Amendment No. 3");

WHEREAS, Company and University entered into an amendment amending the Original Agreement, as amended by Amendment No.1, Amendment No. 2 and Amendment No. 3, on January 21, 2021 ("Amendment No. 4"); and

WHEREAS, by this Amendment No. 5, the Parties wish to further amend the Original Agreement, as amended by Amendment No. 1, Amendment No. 2, Amendment No. 3, and Amendment No. 4, as set forth in Section 2 herein; and

WHEREAS, the Parties desire that all other terms and conditions of the Original Agreement as amended by Amendment No. 1, Amendment No. 2, Amendment No. 3, and Amendment No. 4, remain in full force and effect.

NOW, THEREFORE, COMPANY and UNIVERSITY hereby agree as follows:

1. Capitalized terms used in this Amendment No. 5 shall have the same meaning as those in the Original Agreement, Amendment No. 1, Amendment No. 2, Amendment No. 3, and Amendment No. 4 as the case may be, unless specifically defined otherwise in this Amendment No. 5. All article and section references shall refer to the corresponding Article and Section in the Original Agreement as amended by Amendment No. 1, Amendment No. 2, Amendment No. 3, and Amendment No. 4. All references to the "Agreement" in the Original Agreement, Amendment No. 1, Amendment No. 2, Amendment No. 3, Amendment No. 4, and this Amendment No. 5 shall mean the Original Agreement as amended hereby.

2. Amendments

2.1 Background. A new paragraph is added to Background, Part B of the Original Agreement as follows:

“University and International Centre for Genetic Engineering and Biotechnology (“**ICGEB**”) entered into an interinstitutional agreement with an effective date of December 17, 2020 with a University Reference [\*\*\*] (“**IIA-ICGEB**”) whereby [\*\*\*] has sole control to file, prosecute, maintain, and otherwise protect Licensed Patents with the University Reference designation [\*\*\*] in Section A1 of Exhibit A which are co-owned by University and ICGEB and for which [\*\*\*] has the sole responsibility to seek licensees and grant rights to such Licensed Patents.”

2.2 Section 2.1; Patent License. Section 2.1 (Patent License) of the Original Agreement is hereby amended and restated in its entirety as follows:

“2.1 Patent License. University hereby grants to Company an exclusive (subject only to any rights of the government described in Section 2.6 “The United States Government’s Rights” and to rights of University, Cambridge, and ICGEB described in Section 3 “Rights of University, Limitations”) license under the Licensed Patents to make, have made on Company’s behalf, use, offer to sell, sell, offer to lease or lease, import, or otherwise offer to dispose of Licensed Products in the Territory in the Field of Use. Unless otherwise terminated under Section 9 (Termination), the term of this patent license will begin on the Effective Date and will continue until all Valid Claims expire or are held invalid or unenforceable by a court of competent jurisdiction from which no appeal can be taken.”

2.3 Section 2.5; Limitation of Rights. Section 2.5 (Limitation of Rights) of the Original Agreement is hereby amended and restated in its entirety as follows:

“2.5 Limitation of Rights. No provision of this Agreement grants to Company, by implication, estoppel or otherwise, any rights other than the rights expressly granted it in this Agreement under the Licensed Rights, including any license rights under any other University-owned, Cambridge-owned, or ICGEB-owned technology, copyright, know-how, patent applications, or patents, or any ownership rights in the Licensed Rights.”

2.4 Section 3.1: University’s Rights. Section 3.1 (University’s Rights) of the Original Agreement is hereby amended and restated in its entirety as follows:

“3.1 University’s Rights. University reserves all rights not expressly granted to Company under this Agreement. University retains for itself as well as Cambridge, ICGEB, and any other no-for-profit academic research institutions, an irrevocable, nonexclusive right to practice Licensed Rights for academic research, instructional, or any other academic or non-commercial purpose. University retains for itself an irrevocable, nonexclusive license to practice Licensed Rights for clinical purposes. Cambridge retains for itself an irrevocable, nonexclusive license to practice the University and Cambridge co-owned Licensed Rights, with the University Reference designation [\*\*\*], for clinical purposes. ICGEB retains for itself an irrevocable, nonexclusive license to practice the University and ICGEB co-owned Licensed Rights, with the University Reference designation [\*\*\*], for clinical purposes. Expressly included within this University reservation of rights is to do the following in connection with academic research, instructional, or any other academic or non-commercial purposes: (a) to use the Licensed Rights in sponsored research or collaborative research with any Third Party, but not for any commercial

purpose, and only to the extent that no such Third Party is granted any commercialization rights of any kind under the Licensed Rights or to commercialize Licensed Products, (b) to grant material transfer agreements to the extent that the use of such materials is restricted to academic research, teaching and or other scholarly activities, and (c) to publish any information included in the Licensed Rights or any other information that may result from University's, Cambridge's, or ICGEB's research."

2.5 Section 10.1; Company's Release. Section 10.1 (Company's Release) of the Original Agreement is hereby amended and restated in its entirety as follows:

"10.1. Company's Release. Company hereby releases University, Cambridge, ICGEB, and their regents, employees, and agents forever from any and all suits, actions, claims, liabilities, demands, damages, losses, or expenses (including reasonable attorneys' and investigative expenses) relating to or arising out of [\*\*\*]."

2.6 Section 10.2; Indemnification. Section 10.2 (Indemnification) of the Original Agreement is hereby amended and restated in its entirety as follows:

"10.2 Indemnification. Company will indemnify, defend, and hold harmless University, Cambridge, ICGEB, and their regents, employees, and agents (each, an "**Indemnitee**") from all Third Party suits, actions, claims, liabilities, demands, damages, losses, or expenses (including reasonable attorneys' and investigative expenses), based on University's, Cambridge's, and ICGEB's role in developing or licensing Licensed Rights and relating to or arising out of [\*\*\*] (each, a "**Claim**"), provided that the Company will not have obligations to the extent resulting from [\*\*\*]. In the event of a Claim, the Indemnitee against whom a Claim is brought will: (a) give Company written notice of the Claim within a reasonable period of time after such Indemnitee received notice thereof along with sufficient information for Company to identify the Claim; and (b) cooperate and provide such assistance ([\*\*\*]) as Company may reasonably request in connection with Company's defense, settlement and satisfaction of the Claim. Company will pay or reimburse all costs and expenses reasonably incurred by such Indemnitee to provide any such cooperation and assistance. Any settlement that would admit liability on the part of University, Cambridge, or ICGEB or that would involve any relief other than the payments of monetary damages will be subject to the approval of University and/or Cambridge and/or ICGEB, such approval not to be unreasonably withheld."

2.7 Section 10.3.1; General Insurance Requirement. Section 10.3.1 (General Insurance Requirement) of the Original Agreement is hereby amended and restated in its entirety as follows:

"10.3.1 General Insurance Requirement. Throughout the term of this Agreement, or during such period as the Parties will agree in writing, Company will maintain full force and effect commercial general liability (CGL) insurance and product liability insurance, with single claim limits at an amount customary to Company's business for activities and/or products of a similar nature. Such insurance policy will include coverage for claims that may be asserted by University and/or Cambridge and/or ICGEB against Company under Section 10.2 (Indemnification). Such insurance policy will name the Board of Regents of the University of Washington, the University of Cambridge, and the International Centre for Genetic Engineering and Biotechnology as additional insureds and will require the insurer to deliver written notice to University at the address set forth in Section 13.10 (Notices), at least [\*\*\*] days prior to the

termination of the policy. Company will deliver to University a copy of the certificate of insurance of such policy.”

2.8 Section 11.2; Documents. After the end of Section 11.2 (Documents) of the Original Agreement, the following is hereby inserted:

“In the interinstitutional agreement between University and ICGEB, ICGEB represents that [\*\*\*]. ”\_Company acknowledges that ICGEB was established as a special project of UNIDO, and has legal status, privileges and immunities pursuant to Section 13 of its statutes and international law. University shall not have any liability resulting from ICGEB’s acts or omissions.

2.9 Section 11.3; No Known Infringement; Know-How and Program Materials Rights. After the end of Section 11.3 (No Known Infringement; Know-How and Program Materials Rights) of the Original Agreement, the following is hereby inserted:

“As of the Amendment No. 5 Effective Date, to University’s CoMotion office’s knowledge without any obligation to perform diligence, (a) no claim has been made or is threatened charging ICGEB with infringement of, or claiming that the Licensed Rights infringe any Third Party rights; and (b) no proceedings have been instituted, or are pending or threatened, which challenge ICGEB’s rights in respect to the Licensed Patents or other Licensed Rights.”

2.10 Section 11.4; Disclaimer. Section 11.4 (Disclaimer) of the Original Agreement is hereby amended and restated in its entirety as follows:

**11.4 Disclaimer. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH IN SECTIONS 11.1 (AUTHORITY), 11.2 (DOCUMENTS), AND 11.3 (NO KNOWN INFRINGEMENT) UNIVERSITY, CAMBRIDGE, AND ICGEB DISCLAIM AND EXCLUDE ALL WARRANTIES, EXPRESS AND IMPLIED, CONCERNING EACH LICENSED RIGHT AND EACH LICENSED PRODUCT, INCLUDING WITHOUT LIMITATION, WARRANTIES OF NON-INFRINGEMENT AND THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.** University innovation has been developed as part of research conducted at University. University innovation is experimental in nature and is made “AS IS”, without obligation by University to provide accompanying services or support except as specified in this Agreement. The entire risk as to the quality and performance of University innovation is with Company.”

2.11 Section 11.5; Intellectual Property Disclaimers. Section 11.5 (Intellectual Property Disclaimers) of the Original Agreement is hereby amended and restated in its entirety as follows:

**11.5 Intellectual Property Disclaimers.** University, Cambridge, and ICGEB expressly disclaim any warranties concerning and makes no representation: (a) that the Licensed Patent(s) will be approved or will issue; (b) concerning the validity or scope of any Licensed Right; or (c) that the practice of Licensed Rights, or the manufacture, use, sale, lease or other disposition of a Licensed Product will not infringe or violate a Third Party’s patent, copyright, or other intellectual property right.”

2.12 Section 11.2; Remedy Limitation. Section 11.2 (Remedy Limitation) of the Original Agreement is hereby amended and restated in its entirety as follows:

“11.2 Remedy Limitation. **EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, (A) IN NO EVENT WILL UNIVERSITY AND/OR CAMBRIDGE AND/OR ICGEB BE LIABLE FOR PERSONAL INJURY OR PROPERTY DAMAGES ARISING IN CONNECTION WITH THE ACTIVITIES CONTEMPLATED IN THIS AGREEMENT, AND (B) IN NO EVENT WILL EITHER PARTY AND/OR CAMBRIDGE AND/OR ICGEB BE LIABLE FOR LOST PROFITS, LOST BUSINESS OPPORTUNITY, INVENTORY LOSS, WORK STOPPAGE, LOST DATA OR ANY OTHER RELIANCE OR EXPECTANCY, INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, OF ANY KIND.**”

2.13 Section 13.8 (No Third-Party Beneficiaries). Section 13.8 (No Third-Party Beneficiaries) of the Original Agreement is hereby amended and restated in its entirety as follows:

“13.8 No Third-Party Beneficiaries. Except as identified in parts of this Agreement referencing Cambridge and ICGEB, no provision of this Agreement, express or implied, confers upon any person other than the Parties to this Agreement, any rights, remedies, obligations, or liabilities hereunder. No Sublicensee will have a right to enforce or seek damages under this Agreement.”

2.14 Section 13.12 (Use of University’s Name and Trademarks or the Names of University Faculty, Staff, or Students). Section 13.12 (Use of University’s Name and Trademarks or the Names of University Faculty, Staff, or Students) of the Original Agreement is hereby amended and restated in its entirety as follows:

“13.12 Use of University’s Name and Trademarks or the Names of University Faculty, Staff, or Students. No provision of this Agreement grants Company or Sublicensee any right or license to use the name or trademarks of University or Cambridge or ICGEB or the names or identities of any member of the faculty, staff, or student body of University or Cambridge or ICGEB. Except as provided herein, Company will not use, and will not permit a Sublicensee to use, any such trademarks, names, or identities without University’s and, as the case may be, Cambridge’s or ICGEB’s, and such member’s prior written approval. Notwithstanding the foregoing, Company may provide factual information regarding the existence of this Agreement.”

2.15 Exhibit A, Section A1.1 (Licensed Patents). After the end of the table listing Licensed Patents, [\*\*\*] in Exhibit A, Section A1.1 of the Original Agreement, the following is hereby inserted:

[\*\*\*]

3. Miscellaneous.

3.1 Amendment Fee. Company will pay University a one-time fee of [\*\*\*] US Dollars (\$[\*\*\*]) in consideration for the additional rights granted to Company under this Fifth Amendment, payable within [\*\*\*] days of the Amendment No. 5 Effective Date.

3.2 Effect and Interpretation. This Amendment No. 5 shall be effective for all purposes as of the Amendment No. 5 Effective Date. To the extent that there are any inconsistencies between this



Amendment No. 5 and the Original Agreement as amended by Amendment No. 1, Amendment No. 2, Amendment No. 3, and Amendment No. 4, the terms of this Amendment No. 5 shall supersede those set forth in the Original Agreement, Amendment No. 1, Amendment No. 2, Amendment No. 3, and Amendment No. 4. Except as otherwise expressly modified by this Amendment No. 5, the Original Agreement as amended by Amendment No. 1, Amendment No. 2, Amendment No. 3, and Amendment No. 4 shall remain in full force and effect in accordance with its terms. As of the Amendment No. 5 Effective Date, the term "Agreement" (as used herein and in the Original Agreement, Amendment No. 1, Amendment No. 2, Amendment No. 3, and Amendment No. 4) shall mean the Original Agreement, Amendment No. 1, Amendment No. 2, Amendment No. 3, and Amendment No. 4 as amended by this Amendment No. 5.

3.3 Counterparts. This Amendment No. 5 may be executed in one or more counterparts by original, facsimile or PDF signature, each of which shall be deemed to be an original, but all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, COMPANY and UNIVERSITY have caused this Amendment No. 5 to be executed by their respective duly authorized representatives as of the Amendment No. 5 Effective Date.

**SANA BIOTECHNOLOGY, INC.**

**UNIVERSITY OF WASHINGTON**

By: /s/ Chris Pritchard

By: /s/ Fiona Wills

Name: Chris Pritchard

Name: Fiona Wills

Title: VP, Business Development

Title: Associate Vice Provost

Date: 02/25/2021

Date: 02/25/2021

**CONFIDENTIAL**

**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**

**AMENDMENT NO. 6 TO  
EXCLUSIVE START-UP LICENSE AGREEMENT BETWEEN  
SANA BIOTECHNOLOGY, INC. AND UNIVERSITY OF WASHINGTON**

THIS AMENDMENT NO. 6 (“Amendment No. 6”), with an effective date as of the date of the last signature (“Amendment No. 6 Effective Date”), is entered into by and between Sana Biotechnology, Inc. (“Company”) and University of Washington (“University”).

WHEREAS, Cytocardia, Inc. (“Cytocardia”) and University entered into an Exclusive Start-Up License Agreement for [\*\*\*], with a University Reference [\*\*\*], dated October 9, 2018 (the “Original Agreement”), and amended on November 6, 2019 (“Amendment No. 1”) and July 16, 2020 (“Amendment No. 2”),

WHEREAS, Cytocardia assigned the Original Agreement, as amended by Amendment No. 1 and Amendment No. 2, to Company pursuant to that certain Assignment of License Agreement dated as of effective as of November 11, 2020, and pursuant to which Assignment of License Agreement the parties thereto further amended the Original Agreement, as amended by Amendment No.1 and Amendment No. 2 thereto (“Amendment No. 3”);

WHEREAS, Company and University entered into additional amendments amending the Original Agreement (as amended by Amendment No. 1, Amendment No. 2 and Amendment No. 3) on January 21, 2021 (“Amendment No. 4”) and on February 25, 2021 (“Amendment No. 5”)

WHEREAS, by this Amendment No. 6, the Parties wish to further amend the Original Agreement as amended by Amendment No. 1, Amendment No. 2, Amendment No. 3, Amendment No. 4, and Amendment No. 5, as set forth in Section 2 herein; and

WHEREAS, the Parties desire that all other terms and conditions of the Original Agreement as amended by Amendment No. 1, Amendment No. 2, Amendment No. 3, Amendment No. 4, and Amendment No. 5 remain in full force and effect.

NOW, THEREFORE, COMPANY and UNIVERSITY hereby agree as follows:

1. Capitalized terms used in this Amendment No. 6 shall have the same meaning as those in the Original Agreement, Amendment No. 1, Amendment No. 2, Amendment No. 3, Amendment No. 4, and Amendment No. 5 as the case may be, unless specifically defined otherwise in this Amendment No. 6. All article and section references shall refer to the corresponding Article and Section in the Original Agreement as amended by Amendment No. 1, Amendment No. 2, Amendment No. 3, Amendment No. 4, and Amendment No. 5. All references to the “Agreement” in the Original Agreement, Amendment No. 1, Amendment No. 2, Amendment No. 3, Amendment No. 4, Amendment No. 5, and this Amendment No. 6 shall mean the Original Agreement as amended hereby.

2. Amendments

2.1 Exhibit A, Section A1.1 (Licensed Patents). After the end of the table listing Licensed Patents[\*\*\*] in Exhibit A, Section A1.1 of the Original Agreement, the following is hereby inserted:

**CONFIDENTIAL**

[\*\*\*]

3. Miscellaneous.

3.1 Amendment Fee. Company will pay University a one-time fee of [\*\*\*] US Dollars (\$[\*\*\*]) in consideration for the additional rights granted to Company under this Third Amendment, payable within [\*\*\*] days of the Amendment No. 6 Effective Date.

3.2 Effect and Interpretation. This Amendment No. 6 shall be effective for all purposes as of the Amendment No. 6 Effective Date. To the extent that there are any inconsistencies between this Amendment No. 5 and the Original Agreement as amended by Amendment No. 1, Amendment No. 2, Amendment No. 3, Amendment No. 4, and Amendment No. 5, the terms of this Amendment No. 6 shall supersede those set forth in the Original Agreement, Amendment No. 1, Amendment No. 2, Amendment No. 3, Amendment No. 4, and Amendment No. 5. Except as otherwise expressly modified by this Amendment No. 6, the Original Agreement as amended by Amendment No. 1, Amendment No. 2, Amendment No. 3, Amendment No. 4, and Amendment No. 5 shall remain in full force and effect in accordance with its terms. As of the Amendment No. 6 Effective Date, the term "Agreement" (as used herein and in the Original Agreement, Amendment No. 1, Amendment No. 2, Amendment No. 3, Amendment No. 4 and Amendment No. 5) shall mean the Original Agreement, Amendment No. 1, Amendment No. 2, Amendment No. 3, Amendment No. 4, and Amendment No. 5 as amended by this Amendment No. 6.

3.3 Counterparts. This Amendment No. 6 may be executed in one or more counterparts by original, facsimile or PDF signature, each of which shall be deemed to be an original, but all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, COMPANY and UNIVERSITY have caused this Amendment No. 6 to be executed by their respective duly authorized representatives as of the Amendment No. 6 Effective Date.

**SANA BIOTECHNOLOGY, INC.****UNIVERSITY OF WASHINGTON**By: /s/ Chris PritchardBy: /s/ Fiona Wills

Name: Chris Pritchard

Name: Fiona Wills

Title: VP, Business Development

Title: Associate Vice Provost

Date: 03/11/2021Date: 03/11/2021

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**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**

**AMENDMENT NO. SEVEN (7) TO  
EXCLUSIVE START-UP LICENSE AGREEMENT BETWEEN  
SANA BIOTECHNOLOGY, INC. AND UNIVERSITY OF WASHINGTON**

THIS AMENDMENT NO. 7 ("Amendment No. 7"), with an effective date of as of the date of the last signature ("Amendment No. 7 Effective Date"), is entered into by and between Sana Biotechnology, Inc. ("Company") and University of Washington ("University").

WHEREAS, Cytocardia, Inc. ("Cytocardia") and University entered into an Exclusive Start-Up License Agreement for [\*\*\*], with a University Reference [\*\*\*], dated October 9, 2018 (the "Original Agreement"), and amended on November 6, 2019 ("Amendment No. 1"), and July 16, 2020 ("Amendment No. 2");

WHEREAS, Cytocardia assigned the Original Agreement, as amended by Amendment No. 1 and Amendment No. 2, to Company pursuant to that certain Assignment of License Agreement dated as of effective as of November 11, 2020, and pursuant to which Assignment of License Agreement the parties thereto further amended the Original Agreement, as amended by Amendment No.1 and Amendment No. 2 thereto ("Amendment No. 3");

WHEREAS, Company and University entered into additional amendments amending the Original Agreement (as amended by Amendment No. 1, Amendment No. 2 and Amendment No. 3) on January 21, 2021 ("Amendment No. 4"), on February 25, 2021 ("Amendment No. 5"), and on March 11, 2021 ("Amendment No. 6"); and

WHEREAS, by this Amendment No. 7, the Parties wish to further amend the Original Agreement, as amended by Amendment No. 1, Amendment No. 2, Amendment No. 3, Amendment No. 4, Amendment No. 5, and Amendment No. 6, as set forth in Section 2 herein; and

WHEREAS, the Parties desire that all other terms and conditions of the Original Agreement as amended by Amendment No. 1, Amendment No. 2, Amendment No. 3, Amendment No. 4, Amendment No. 5, and Amendment No. 6, remain in full force and effect.

NOW, THEREFORE, COMPANY and UNIVERSITY hereby agree as follows:

1. Capitalized terms used in this Amendment No. 7 shall have the same meaning as those in the Original Agreement, Amendment No. 1, Amendment No. 2, Amendment No. 3, Amendment No. 4, Amendment No. 5, and Amendment No. 6, as the case may be, unless specifically defined otherwise in this Amendment No. 7. All article and section references shall refer to the corresponding Article and Section in the Original Agreement as amended by Amendment No. 1, Amendment No. 2, Amendment No. 3, Amendment No. 4, Amendment No. 5, and Amendment No. 6. All references to the "Agreement" in the Original Agreement, Amendment No. 1, Amendment No. 2, Amendment No. 3, Amendment No. 4, Amendment No. 5, Amendment No. 6, and this Amendment No. 7 shall mean the Original Agreement as amended hereby.

2. Amendments

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2.1 Background. A new paragraph is added to Background, Part B of the Original Agreement as follows:

“University and Vanderbilt University (“Vanderbilt”) entered into an interinstitutional agreement with an effective date of February 25, 2021 with a University Reference [\*\*\*] (“**IIA-Vanderbilt**”) whereby [\*\*\*] has sole control to file, prosecute, maintain, and otherwise protect Licensed Patents with the University Reference designation [\*\*\*] in Section A1 of Exhibit A which are co-owned by University and Vanderbilt and for which [\*\*\*] has the sole responsibility to seek licensees and grant rights to such Licensed Patents.”

2.2 Section 2.1; Patent License. Section 2.1 (Patent License) of the Original Agreement is hereby amended and restated in its entirety as follows:

“2.1 Patent License. University hereby grants to Company an exclusive (subject only to any rights of the government described in Section 2.6 “The United States Government’s Rights” and to rights of University, Cambridge, ICGEB, and Vanderbilt described in Section 3 “Rights of University, Limitations”) license under the Licensed Patents to make, have made on Company’s behalf, use, offer to sell, sell, offer to lease or lease, import, or otherwise offer to dispose of Licensed Products in the Territory in the Field of Use. Unless otherwise terminated under Section 9 (Termination), the term of this patent license will begin on the Effective Date and will continue until all Valid Claims expire or are held invalid or unenforceable by a court of competent jurisdiction from which no appeal can be taken.”

2.3 Section 2.5; Limitation of Rights. Section 2.5 (Limitation of Rights) of the Original Agreement is hereby amended and restated in its entirety as follows:

“2.5 Limitation of Rights. No provision of this Agreement grants to Company, by implication, estoppel or otherwise, any rights other than the rights expressly granted it in this Agreement under the Licensed Rights, including any license rights under any other University-owned, Cambridge-owned, ICGEB-owned technology, or Vanderbilt-owned technology, copyright, know-how, patent applications, or patents, or any ownership rights in the Licensed Rights.”

2.4 Section 3.1: University’s Rights. Section 3.1 (University’s Rights) of the Original Agreement is hereby amended and restated in its entirety as follows:

“3.1 University’s Rights. University reserves all rights not expressly granted to Company under this Agreement. University retains for itself as well as Cambridge, ICGEB, Vanderbilt and any other no-for-profit academic research institutions, an irrevocable, nonexclusive right to practice Licensed Rights for academic research, instructional, or any other academic or non-commercial purpose. University retains for itself an irrevocable, nonexclusive license to practice Licensed Rights for clinical purposes. Cambridge retains for itself an irrevocable, nonexclusive license to practice the University and Cambridge co-owned Licensed Rights, with the University Reference designation [\*\*\*], for clinical purposes. ICGEB retains for itself an irrevocable, nonexclusive license to practice the University and ICGEB co-owned Licensed Rights, with the University Reference designation [\*\*\*], for clinical purposes. Vanderbilt retains for itself an irrevocable, nonexclusive license to practice the University and Vanderbilt co-owned Licensed Rights, with the University Reference designation [\*\*\*], for clinical purposes. Expressly included within this University reservation of rights is to do the following in connection with academic research, instructional, or any other academic or non-commercial purposes: (a) to use

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the Licensed Rights in sponsored research or collaborative research with any Third Party, but not for any commercial purpose, and only to the extent that no such Third Party is granted any commercialization rights of any kind under the Licensed Rights or to commercialize Licensed Products, (b) to grant material transfer agreements to the extent that the use of such materials is restricted to academic research, teaching and or other scholarly activities, and (c) to publish any information included in the Licensed Rights or any other information that may result from University's, Cambridge's, ICGEB's, or Vanderbilt's research."

2.5 Section 10.1; Company's Release. Section 10.1 (Company's Release) of the Original Agreement is hereby amended and restated in its entirety as follows:

"10.1. Company's Release. Company hereby releases University, Cambridge, ICGEB, Vanderbilt, and their regents, employees, and agents forever from any and all suits, actions, claims, liabilities, demands, damages, losses, or expenses (including reasonable attorneys' and investigative expenses) relating to or arising out of [\*\*\*]."

2.6 Section 10.2; Indemnification. Section 10.2 (Indemnification) of the Original Agreement is hereby amended and restated in its entirety as follows:

"10.2 Indemnification. Company will indemnify, defend, and hold harmless University, Cambridge, ICGEB, Vanderbilt, and their regents, trustees, directors, officers, employees, faculty, postdocs, students, affiliated investigators, and agents and their respective successors, heirs, and assigns, (each, an "**Indemnitee**") from all Third Party suits, actions, claims, liabilities, demands, damages, losses, or expenses (including reasonable attorneys' and investigative expenses), based on University's, Cambridge's, ICGEB's, and Vanderbilt's role in developing or licensing Licensed Rights and relating to or arising out of [\*\*\*] (each, a "**Claim**"), provided that the Company will not have obligations to the extent resulting from [\*\*\*]. In the event of a Claim, the Indemnitee against whom a Claim is brought will: (a) give Company written notice of the Claim within a reasonable period of time after such Indemnitee received notice thereof along with sufficient information for Company to identify the Claim; and (b) cooperate and provide such assistance ([\*\*\*]) as Company may reasonably request in connection with Company's defense, settlement and satisfaction of the Claim. Company will pay or reimburse all costs and expenses reasonably incurred by such Indemnitee to provide any such cooperation and assistance. Any settlement that would admit liability on the part of University, Cambridge, ICGEB, or Vanderbilt, or that would involve any relief other than the payments of monetary damages will be subject to the approval of University and/or Cambridge and/or ICGEB and/or Vanderbilt, such approval not to be unreasonably withheld."

2.7 Section 10.3.1; General Insurance Requirement. Section 10.3.1 (General Insurance Requirement) of the Original Agreement is hereby amended and restated in its entirety as follows:

"10.3.1 General Insurance Requirement. Throughout the term of this Agreement, or during such period as the Parties will agree in writing, Company will maintain full force and effect commercial general liability (CGL) insurance and product liability insurance, with single claim limits at an amount customary to Company's business for activities and/or products of a similar nature. Such insurance policy will include coverage for claims that may be asserted by University and/or Cambridge and/or ICGEB and/or Vanderbilt against Company under Section 10.2 (Indemnification). Such insurance policy will name the Board of Regents of the University of Washington, the University of Cambridge, and the International Centre for Genetic Engineering and Biotechnology, and Vanderbilt University as additional insureds and will

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require the insurer to deliver written notice to University at the address set forth in Section 13.10 (Notices), at least [\*\*\*] days prior to the termination of the policy. Company will deliver to University a copy of the certificate of insurance of such policy.”

2.10 Section 11.4; Disclaimer. Section 11.4 (Disclaimer) of the Original Agreement is hereby amended and restated in its entirety as follows:

“11.4 Disclaimer. **EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH IN SECTIONS 11.1 (AUTHORITY), 11.2 (DOCUMENTS), AND 11.3 (NO KNOWN INFRINGEMENT) UNIVERSITY, CAMBRIDGE, ICGEB, AND VANDERBILT DISCLAIM AND EXCLUDE ALL WARRANTIES, EXPRESS AND IMPLIED, CONCERNING EACH LICENSED RIGHT AND EACH LICENSED PRODUCT, INCLUDING WITHOUT LIMITATION, WARRANTIES OF NON-INFRINGEMENT AND THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.** University innovation has been developed as part of research conducted at University. University innovation is experimental in nature and is made “AS IS”, without obligation by University to provide accompanying services or support except as specified in this Agreement. The entire risk as to the quality and performance of University innovation is with Company.”

2.11 Section 11.5; Intellectual Property Disclaimers. Section 11.5 (Intellectual Property Disclaimers) of the Original Agreement is hereby amended and restated in its entirety as follows:

“11.5 Intellectual Property Disclaimers. University, Cambridge, ICGEB, and Vanderbilt expressly disclaim any warranties concerning and makes no representation: (a) that the Licensed Patent(s) will be approved or will issue; (b) concerning the validity or scope of any Licensed Right; or (c) that the practice of Licensed Rights, or the manufacture, use, sale, lease or other disposition of a Licensed Product will not infringe or violate a Third Party’s patent, copyright, or other intellectual property right.”

2.12 Section 11.2; Remedy Limitation. Section 11.2 (Remedy Limitation) of the Original Agreement is hereby amended and restated in its entirety as follows:

“11.2 Remedy Limitation. **EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, (A) IN NO EVENT WILL UNIVERSITY AND/OR CAMBRIDGE AND/OR ICGEB AND/OR VANDERBILT BE LIABLE FOR PERSONAL INJURY OR PROPERTY DAMAGES ARISING IN CONNECTION WITH THE ACTIVITIES CONTEMPLATED IN THIS AGREEMENT, AND (B) IN NO EVENT WILL EITHER PARTY AND/OR CAMBRIDGE AND/OR ICGEB BE LIABLE FOR LOST PROFITS, LOST BUSINESS OPPORTUNITY, INVENTORY LOSS, WORK STOPPAGE, LOST DATA OR ANY OTHER RELIANCE OR EXPECTANCY, INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, OF ANY KIND.**”

2.13 Section 13.8 (No Third-Party Beneficiaries). Section 13.8 (No Third-Party Beneficiaries) of the Original Agreement is hereby amended and restated in its entirety as follows:

“13.8 No Third-Party Beneficiaries. Except as identified in parts of this Agreement referencing Cambridge, ICGEB, and Vanderbilt, no provision of this Agreement, express or implied, confers upon any person other than the Parties to this Agreement, any rights, remedies,

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obligations, or liabilities hereunder. No Sublicensee will have a right to enforce or seek damages under this Agreement.”

2.14 Section 13.12 (Use of University’s Name and Trademarks or the Names of University Faculty, Staff, or Students). Section 13.12 (Use of University’s Name and Trademarks or the Names of University Faculty, Staff, or Students) of the Original Agreement is hereby amended and restated in its entirety as follows:

“13.12 Use of University’s Name and Trademarks or the Names of University Faculty, Staff, or Students. No provision of this Agreement grants Company or Sublicensee any right or license to use the name or trademarks of University or Cambridge or ICGEB or Vanderbilt or the names or identities of any member of the faculty, staff, or student body of University or Cambridge or ICGEB or Vanderbilt. Except as provided herein, Company will not use, and will not permit a Sublicensee to use, any such trademarks, names, or identities without University’s and, as the case may be, Cambridge’s, ICGEB’s, or Vanderbilt’s, and such member’s prior written approval. Notwithstanding the foregoing, Company may provide factual information regarding the existence of this Agreement.”

2.15 Exhibit A, Section A1.1 (Licensed Patents). After the end of the table listing Licensed Patents, [\*\*\*] in Exhibit A, Section A1.1 of the Original Agreement, the following is hereby inserted:

[\*\*\*]

3. Miscellaneous.

3.1 Amendment Fee. Company will pay University a one-time fee of [\*\*\*] US Dollars (\$[\*\*\*]) in consideration for the additional rights granted to Company under this Seventh Amendment, payable within [\*\*\*] days of the Amendment No. 7 Effective Date.

3.2 Effect and Interpretation. This Amendment No. 7 shall be effective for all purposes as of the Amendment No. 7 Effective Date. To the extent that there are any inconsistencies between this Amendment No. 7 and the Original Agreement as amended by Amendment No. 1, Amendment No. 2, Amendment No. 3, Amendment No. 4, Amendment No. 5, and Amendment No. 6, the terms of this Amendment No. 7 shall supersede those set forth in the Original Agreement, Amendment No. 1, Amendment No. 2, Amendment No. 3, Amendment No. 4, Amendment No. 5, and Amendment No. 6. Except as otherwise expressly modified by this Amendment No. 7, the Original Agreement as amended by Amendment No. 1, Amendment No. 2, Amendment No. 3, Amendment No. 4, Amendment No. 5, and Amendment No. 6, shall remain in full force and effect in accordance with its terms. As of the Amendment No. 7 Effective Date, the term “Agreement” (as used herein and in the Original Agreement, Amendment No. 1, Amendment No. 2, Amendment No. 3, Amendment No. 4, Amendment No. 5, and Amendment No. 6) shall mean the Original Agreement, Amendment No. 1, Amendment No. 2, Amendment No. 3, Amendment No. 4, Amendment No. 5, and Amendment No. 6, as amended by this Amendment No. 7.

3.3 Counterparts. This Amendment No. 7 may be executed in one or more counterparts by original, facsimile or PDF signature, each of which shall be deemed to be an original, but all of which together shall constitute one and the same instrument.





**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**

**AMENDMENT NO. EIGHT (8) TO  
EXCLUSIVE START-UP LICENSE AGREEMENT BETWEEN  
SANA BIOTECHNOLOGY, INC. AND UNIVERSITY OF WASHINGTON**

THIS AMENDMENT NO. 8 ("Amendment No. 8"), with an effective the date of last signature ("Amendment No. 8 Effective Date"), is entered into by and between Sana Biotechnology, Inc. ("Company") and University of Washington ("University").

WHEREAS, Cytocardia, Inc. ("Cytocardia") and University entered into an Exclusive Start-Up License Agreement for [\*\*\*], with a University Reference [\*\*\*], dated October 9, 2018 (the "Original Agreement"), and amended on November 6, 2019 ("Amendment No. 1"), and July 16, 2020 ("Amendment No. 2");

WHEREAS, Cytocardia assigned the Original Agreement, as amended by Amendment No. 1 and Amendment No. 2, to Company pursuant to that certain Assignment of License Agreement dated as of effective as of November 11, 2020, and pursuant to which Assignment of License Agreement the parties thereto further amended the Original Agreement, as amended by Amendment No.1 and Amendment No. 2 thereto ("Amendment No. 3");

WHEREAS, Company and University entered into additional amendments amending the Original Agreement (as amended by Amendment No. 1, Amendment No. 2 and Amendment No. 3) on January 21, 2021 ("Amendment No. 4"), on February 25, 2021 ("Amendment No. 5"), on March 11, 2021 ("Amendment No. 6"); and April 14, 2021 ("Amendment No. 7");

WHEREAS, Company and University entered into that certain Exclusive Option Agreement dated as of May 25, 2021 ("Option Agreement") whereby University granted Company an option to amend the Existing License Agreement to add University Patents (as defined in the Option Agreement) to the Licensed Patents under the License Agreement, and whereas Company now wishes to exercise its option and enter into this current Amendment No. 8 for the grant of the exclusive license to such Licensed Patents in accordance herewith;

WHEREAS, by this Amendment No. 8, the Parties wish to further amend the Original Agreement, as amended by Amendment No. 1, Amendment No. 2, Amendment No. 3, Amendment No. 4, Amendment No. 5, Amendment No. 6, and Amendment No. 7 as set forth in Section 2 herein; and

WHEREAS, the Parties desire that all other terms and conditions of the Original Agreement as amended by Amendment No. 1, Amendment No. 2, Amendment No. 3, Amendment No. 4, Amendment No. 5, Amendment No. 6, and Amendment No. 7 remain in full force and effect.

NOW, THEREFORE, COMPANY and UNIVERSITY hereby agree as follows:

1. Capitalized terms used in this Amendment No. 8 shall have the same meaning as those in the Original Agreement, Amendment No. 1, Amendment No. 2, Amendment No. 3, Amendment No. 4, Amendment No. 5, Amendment No. 6, and Amendment No. 7 as the case may be, unless specifically defined otherwise in this Amendment No. 8. All article and section references shall refer to the corresponding Article and Section in the Original Agreement as amended by Amendment No. 1,

Amendment No. 2, Amendment No. 3, Amendment No. 4, Amendment No. 5, Amendment No. 6, and Amendment No. 7. All references to the “Agreement” in the Original Agreement, Amendment No. 1, Amendment No. 2, Amendment No. 3, Amendment No. 4, Amendment No. 5, Amendment No. 6, Amendment No. 7, and this Amendment No. 8 shall mean the Original Agreement as amended hereby.

2. Amendment

2.1 Exhibit A, Section A1.1 (Licensed Patents). The following is hereby added to the end of the existing table listing Licensed Patents, [\*\*\*] in Exhibit A, Section A1.1 of the Original Agreement:

[\*\*\*]

3. Miscellaneous.

3.1 Amendment Fee. Company will pay University a one-time fee of [\*\*\*] US Dollars (\$[\*\*\*]) in consideration for the additional rights granted to Company under this Eighth Amendment, payable within [\*\*\*] days of the Amendment No. 8 Effective Date.

3.2 Effect and Interpretation. This Amendment No. 8 shall be effective for all purposes as of the Amendment No. 8 Effective Date. To the extent that there are any inconsistencies between this Amendment No. 5 and the Original Agreement as amended by Amendment No. 1, Amendment No. 2, Amendment No. 3, Amendment No. 4, Amendment No. 5, Amendment No. 6, and Amendment No. 7 the terms of this Amendment No. 8 shall supersede those set forth in the Original Agreement, Amendment No. 1, Amendment No. 2, Amendment No. 3, Amendment No. 4, Amendment No. 5, Amendment No. 6, and Amendment No. 7. Except as otherwise expressly modified by this Amendment No. 8, the Original Agreement as amended by Amendment No. 1, Amendment No. 2, Amendment No. 3, Amendment No. 4, Amendment No. 5, Amendment No. 6, and Amendment No. 7 shall remain in full force and effect in accordance with its terms. As of the Amendment No. 8 Effective Date, the term “Agreement” (as used herein and in the Original Agreement, Amendment No. 1, Amendment No. 2, Amendment No. 3, Amendment No. 4, Amendment No. 5, Amendment No. 6, and Amendment No. 7) shall mean the Original Agreement, Amendment No. 1, Amendment No. 2, Amendment No. 3, Amendment No. 4, Amendment No. 5, Amendment No. 6, and Amendment No. 7 as amended by this Amendment No. 8.

3.3 Counterparts. This Amendment No. 8 may be executed in one or more counterparts by original, facsimile or PDF signature, each of which shall be deemed to be an original, but all of which together shall constitute one and the same instrument.

Signatures follow on the next page.

IN WITNESS WHEREOF, COMPANY and UNIVERSITY have caused this Amendment No. 8 to be executed by their respective duly authorized representatives as of the Amendment No. 8 Effective Date.

**SANA BIOTECHNOLOGY, INC.**

**UNIVERSITY OF WASHINGTON**

By: /s/ Christian Hordo

By: /s/ Fiona Wills

Name: Christian Hordo

Name: Fiona Wills

Title: CBO

Title: Associate Vice Provost

Date: 7/20/2021

Date: 7/20/2021

**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**

**AMENDMENT NO. NINE (9) TO [\*\*\*]  
EXCLUSIVE START-UP LICENSE AGREEMENT BETWEEN  
SANA BIOTECHNOLOGY, INC. AND UNIVERSITY OF WASHINGTON**

THIS AMENDMENT NO. 9 ("Amendment No. 9"), with an effective the date of last signature ("Amendment No. 9 Effective Date"), is entered into by and between Sana Biotechnology, Inc. ("Company") and University of Washington ("University").

WHEREAS, Cytocardia, Inc. ("Cytocardia") and University entered into an Exclusive Start-Up License Agreement for [\*\*\*], with a University Reference [\*\*\*], dated October 9, 2018 (the "Original Agreement"), and amended on November 6, 2019 ("Amendment No. 1"), and July 16, 2020 ("Amendment No. 2");

WHEREAS, Cytocardia assigned the Original Agreement, as amended by Amendment No. 1 and Amendment No. 2, to Company pursuant to that certain Assignment of License Agreement dated as of effective as of November 11, 2020, and pursuant to which Assignment of License Agreement the parties thereto further amended the Original Agreement, as amended by Amendment No.1 and Amendment No. 2 thereto ("Amendment No. 3");

WHEREAS, Company and University entered into additional amendments amending the Original Agreement (as amended by Amendment No. 1, Amendment No. 2 and Amendment No. 3) on January 21, 2021 ("Amendment No. 4"), on February 25, 2021 ("Amendment No. 5"), on March 11, 2021 ("Amendment No. 6"), on April 14, 2021 ("Amendment No. 7"), and on July 20, 2021 ("Amendment No. 8");

WHEREAS, University to file, and Company agreed to license, [\*\*\*] to replace [\*\*\*] which is listed in Exhibit A, Section A1.1 of Amendment No. 5;

WHEREAS, University agreed to file [\*\*\*] ([\*\*\*]application) in UW ref no. [\*\*\*], which previously included only [\*\*\*] listed in Exhibit A, Section A1.1 of Amendment No. 6, and Company agreed license the [\*\*\*] application;

WHEREAS, by this Amendment No. 9, the Parties wish to further amend the Original Agreement, as amended by Amendment No. 1, Amendment No. 2, Amendment No. 3, Amendment No. 4, Amendment No. 5, Amendment No. 6, Amendment No. 7, and Amendment No. 8 as set forth in Section 2 herein; and

WHEREAS, the Parties desire that all other terms and conditions of the Original Agreement as amended by Amendment No. 1, Amendment No. 2, Amendment No. 3, Amendment No. 4, Amendment No. 5, Amendment No. 6, Amendment No. 7, and Amendment No. 8 remain in full force and effect.

NOW, THEREFORE, COMPANY and UNIVERSITY hereby agree as follows:

1. Capitalized terms used in this Amendment No. 9 shall have the same meaning as those in the Original Agreement, Amendment No. 1, Amendment No. 2, Amendment No. 3, Amendment No. 4, Amendment No. 5, Amendment No. 6, Amendment No. 7, and Amendment No. 8 as the case may be, unless specifically defined otherwise in this Amendment No. 9. All article and section references shall refer to the corresponding Article and Section in the Original Agreement as amended by Amendment No. 1, Amendment No. 2, Amendment No. 3, Amendment No. 4, Amendment No. 5, Amendment No. 6, Amendment No. 7, and Amendment No. 8.

2. Amendment

2.1 Exhibit A, Section A1.1 (Licensed Patents). The following is hereby added to the end of the existing table listing Licensed Patents, [\*\*\*] in Exhibit A, Section A1.1 of the Original Agreement:

[\*\*\*]

3. Miscellaneous.

3.1 Effect and Interpretation. This Amendment No. 9 shall be effective for all purposes as of the Amendment No. 9 Effective Date. To the extent that there are any inconsistencies between this Amendment No. 9 and the Original Agreement as amended by Amendment No. 1, Amendment No. 2, Amendment No. 3, Amendment No. 4, Amendment No. 5, Amendment No. 6, Amendment No. 7, and Amendment No. 8, the terms of this Amendment No. 9 shall supersede those set forth in the Original Agreement, Amendment No. 1, Amendment No. 2, Amendment No. 3, Amendment No. 4, Amendment No. 5, Amendment No. 6, Amendment No. 7, and Amendment No. 8. Except as otherwise expressly modified by this Amendment No. 9, the Original Agreement as amended by Amendment No. 1, Amendment No. 2, Amendment No. 3, Amendment No. 4, Amendment No. 5, Amendment No. 6, Amendment No. 7, and Amendment No. 8 shall remain in full force and effect in accordance with its terms. As of the Amendment No. 9 Effective Date, the term “Agreement” (as used herein and in the Original Agreement, Amendment No. 1, Amendment No. 2, Amendment No. 3, Amendment No. 4, Amendment No. 5, Amendment No. 6, Amendment No. 7, and Amendment No. 8) shall mean the Original Agreement, Amendment No. 1, Amendment No. 2, Amendment No. 3, Amendment No. 4, Amendment No. 5, Amendment No. 6, Amendment No. 7, and Amendment No. 8 as amended by this Amendment No. 9.

4. Counterparts. This Amendment No. 9 may be executed in one or more counterparts by original, facsimile or PDF signature, each of which shall be deemed to be an original, but all of which together shall constitute one and the same instrument.

Signatures follow on the next page.

IN WITNESS WHEREOF, COMPANY and UNIVERSITY have caused this Amendment No. 9 to be executed by their respective duly authorized representatives as of the Amendment No. 9 Effective Date.

**SANA BIOTECHNOLOGY, INC.**

**UNIVERSITY OF WASHINGTON**

By: /s/ Chris Pritchard, PhD

By: /s/ Fiona Wills

Name: Chris Pritchard, PhD

Name: Fiona Wills

Title: VP, Business Development

Title: Associate Vice Provost

Date: 9/9/2021

Date: 9/9/2021

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

**AMENDMENT NO. 10 TO  
EXCLUSIVE START-UP LICENSE AGREEMENT BETWEEN  
CYTOCARDIA, INC. AND UNIVERSITY OF WASHINGTON**

THIS AMENDMENT NO. 10 ("Amendment No. 10"), with an effective date of the date of last signature ("Amendment No. 10 Effective Date"), is entered into by and between Sana Biotechnology, Inc. ("Company") and University of Washington ("University").

WHEREAS, Cytocardia, Inc. ("Cytocardia") and University entered into an Exclusive Start-Up License Agreement for [\*\*\*], with a University Reference [\*\*\*], dated October 9, 2018 (the "Original Agreement"), and amended on November 6, 2019 ("Amendment No. 1"), and July 16, 2020 ("Amendment No. 2");

WHEREAS, Cytocardia assigned the Original Agreement, as amended by Amendment No. 1 and Amendment No. 2, to Company pursuant to that certain Assignment of License Agreement dated as of effective as of November 11, 2020, and pursuant to which Assignment of License Agreement the parties thereto further amended the Original Agreement, as amended by Amendment No.1 and Amendment No. 2 thereto ("Amendment No. 3");

WHEREAS, Company and University entered into additional amendments amending the Original Agreement (as amended by Amendment No. 1, Amendment No. 2 and Amendment No. 3) on January 21, 2021 ("Amendment No. 4"), on February 25, 2021 ("Amendment No. 5"), on March 11, 2021 ("Amendment No. 6"); on April 14, 2021("Amendment No. 7"); on July 20, 2021 ("Amendment No. 8"), and on September 9, 2021 ("Amendment No. 9").

WHEREAS, by this Amendment No. 10, the Parties wish to further amend the Original Agreement, as amended by Amendment No. 1, Amendment No. 2, Amendment No. 3, Amendment No. 4, Amendment No. 5, Amendment No. 6, Amendment No. 7, Amendment No. 8, and Amendment No. 9 (collectively, the "Prior Amendments") as set forth in Section 2 herein; and

WHEREAS, the Parties desire that all other terms and conditions of the Original Agreement as amended by the Prior Amendments remain in full force and effect.

WHEREAS, the Parties desire that all other terms and conditions of the Original Agreement and the Prior Amendments remain in full force and effect;

NOW, THEREFORE, COMPANY and UNIVERSITY hereby agree as follows:

1. Capitalized terms used in this Amendment No. 10 shall have the same meaning as those in the Original Agreement and the Prior Amendments, as the case may be, unless specifically defined otherwise in this Amendment No. 10. All article and section references shall refer to the corresponding Article and Section in the Original Agreement the Prior Amendments. All references to the "Agreement" in the Original Agreement, the Prior Amendments, and this Amendment No. 10 shall mean the Original Agreement as amended hereby.

2. Amendment



2.1 Exhibit D “Licensed Program Materials.” Exhibit D of the Agreement is hereby amended to list new items. The following is added to the table listing Licensed Program Materials.

[\*\*\*]

3. Fee. In consideration for the rights granted to Company herein, and in further consideration of the University labor required to prepare and transfer the Licensed Program Materials, Company shall pay to University a one-time, non-refundable fee of [\*\*\*] Dollars (\$[\*\*\*]) within [\*\*\*] days of invoice from UW following the Effective Date.

4. Miscellaneous.

4.1 Effect and Interpretation. This Amendment No. 10 shall be effective for all purposes as of the Amendment No. 10 Effective Date. To the extent that there are any inconsistencies between this Amendment No. 10 and the Original Agreement and the Prior Amendments, the terms of this Amendment No. 10 shall supersede those set forth in the Original Agreement the Prior Amendments. Except as otherwise expressly modified by this Amendment No. 10, the Original Agreement and the Prior Amendments shall remain in full force and effect in accordance with their terms. As of the Amendment No. 10 Effective Date, the term “Agreement” (as used herein and in the Original Agreement and the Prior Amendments) shall mean the Original Agreement and the Prior Amendments as amended by this Amendment No. 10.

4.2 Counterparts. This Amendment No. 10 may be executed in one or more counterparts by original, facsimile or PDF signature, each of which shall be deemed to be an original, but all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, COMPANY and UNIVERSITY have caused this Amendment No. 10 to be executed by their respective duly authorized representatives as of the Amendment No. 10 Effective Date.

**SANA BIOTECHNOLOGY, INC.**

**UNIVERSITY OF WASHINGTON**

By: /s/ Steve Harr  
Name: Steve Harr  
Title: CEO  
Date: 10/30/2021

By: /s/ Fiona Wills  
Name: Fiona Wills  
Title: Associate Vice Provost  
Date: 10/30/2021

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

**AMENDMENT NO. 11 TO  
EXCLUSIVE START-UP LICENSE AGREEMENT BETWEEN  
CYTOCARDIA, INC. AND UNIVERSITY OF WASHINGTON**

THIS AMENDMENT NO. 11 ("Amendment No. 11"), with an effective date of the date of last signature ("Amendment No. 11 Effective Date"), is entered into by and between Sana Biotechnology, Inc. ("Company") and University of Washington ("University").

WHEREAS, Cytocardia, Inc. ("Cytocardia") and University entered into an Exclusive Start-Up License Agreement for [\*\*\*], with a University Reference [\*\*\*], dated October 9, 2018 (the "Original Agreement"), and amended on November 6, 2019 ("Amendment No. 1"), and July 16, 2020 ("Amendment No. 2");

WHEREAS, Cytocardia assigned the Original Agreement, as amended by Amendment No. 1 and Amendment No. 2, to Company pursuant to that certain Assignment of License Agreement dated as of effective as of November 11, 2020, and pursuant to which Assignment of License Agreement the parties thereto further amended the Original Agreement, as amended by Amendment No.1 and Amendment No. 2 thereto ("Amendment No. 3");

WHEREAS, Company and University entered into additional amendments amending the Original Agreement (as amended by Amendment No. 1, Amendment No. 2 and Amendment No. 3) on January 21, 2021 ("Amendment No. 4"), on February 25, 2021 ("Amendment No. 5"), on March 11, 2021 ("Amendment No. 6"); on April 14, 2021("Amendment No. 7"); on July 20, 2021 ("Amendment No. 8"), on September 9, 2021 ("Amendment No. 9") and on October 30, 2021.

WHEREAS, by this Amendment No. 11, the Parties wish to further amend the Original Agreement, as amended by Amendment No. 1, Amendment No. 2, Amendment No. 3, Amendment No. 4, Amendment No. 5, Amendment No. 6, Amendment No. 7, Amendment No. 8, Amendment No. 9 and Amendment No. 10 (collectively, the "Prior Amendments") as set forth in Section 2 herein; and

WHEREAS, the Parties desire that all other terms and conditions of the Original Agreement as amended by the Prior Amendments remain in full force and effect.

WHEREAS, the Parties desire that all other terms and conditions of the Original Agreement and the Prior Amendments remain in full force and effect;

NOW, THEREFORE, COMPANY and UNIVERSITY hereby agree as follows:

1. Capitalized terms used in this Amendment No. 11 shall have the same meaning as those in the Original Agreement and the Prior Amendments, as the case may be, unless specifically defined otherwise in this Amendment No. 11. All article and section references shall refer to the corresponding Article and Section in the Original Agreement the Prior Amendments. All references to the "Agreement" in the Original Agreement, the Prior Amendments, and this Amendment No. 11 shall mean the Original Agreement as amended hereby.

2. Amendment

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2.1 Exhibit A, Section A.3.3. The first sentence of Section A.3.3 of Exhibit A is hereby deleted and replaced in its entirety by the following:

“A.3.3. Financial Milestones. Company will pay to University the following non-cumulated, non-creditable, and non-refundable milestone achievement payments within [\*\*\*] days of achieving the corresponding milestone in all fields within the Field of Use, except for the field of [\*\*\*] using (a) any [\*\*\*], (b) any [\*\*\*] or (c) any progeny of the foregoing ((a) or (b)), whether achieved by Company or a Sublicensee.”

4. Miscellaneous.

4.1 Effect and Interpretation. This Amendment No. 11 shall be effective for all purposes as of the Amendment No. 11 Effective Date. To the extent that there are any inconsistencies between this Amendment No. 11 and the Original Agreement and the Prior Amendments, the terms of this Amendment No. 11 shall supersede those set forth in the Original Agreement the Prior Amendments. Except as otherwise expressly modified by this Amendment No. 11, the Original Agreement and the Prior Amendments shall remain in full force and effect in accordance with their terms. As of the Amendment No. 11 Effective Date, the term “Agreement” (as used herein and in the Original Agreement and the Prior Amendments) shall mean the Original Agreement and the Prior Amendments as amended by this Amendment No. 11.

4.2 Counterparts. This Amendment No. 11 may be executed in one or more counterparts by original, facsimile or PDF signature, each of which shall be deemed to be an original, but all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, COMPANY and UNIVERSITY have caused this Amendment No. 11 to be executed by their respective duly authorized representatives as of the Amendment No. 11 Effective Date.

**SANA BIOTECHNOLOGY, INC.**

**UNIVERSITY OF WASHINGTON**

By: /s/ Christian Hordo  
(Signature)  
Name: Christian Hordo  
Title: Chief Business Officer  
Date: July 14, 2022

By: /s/ Fiona Wills  
(Signature)  
Name: Fiona Wills  
Title: Associate Vice Provost  
Date: 7/14/2022



September 8, 2022

Bernard Cassidy

[\*\*\*]

[\*\*\*]

Sent via email to [\*\*\*]

**Re: Employment Terms**

Dear Barney:

Sana Biotechnology, Inc. (the "Company"), is pleased to offer you fulltime employment in the exempt position of **Executive Vice President, General Counsel** effective as of **September 12, 2022** (the date you actually commence employment, your "Commencement Date"), in which you will be responsible for such duties as are normally associated with such position or as otherwise determined by the Chief Executive Officer of the Company. You will report to Steve Har, the Chief Executive Officer of the Company (the "CEO") and will be initially headquartered in our Seattle – WA – Blaine offices, or such other location as the Company may designate, except for such travel as may be necessary to fulfill your responsibilities. In the course of your employment with Company, you will be subject to and required to comply with all company policies, and applicable laws and regulations.

You will be paid a base salary at the bi-weekly rate of **\$17,307.69** (subject to required tax withholding and other authorized deductions), equivalent to **\$450,000** on an annualized basis. Your base salary will be payable in accordance with the Company's standard payroll policies and subject to adjustment pursuant to the Company's policies as in effect from time to time. This position is exempt from overtime.

In addition to your base salary, you will be eligible for an annual cash bonus, at the discretion of the Board of Directors of the Company (the "Board"). Your target annual bonus shall be **40%** of your base salary, but the actual amount of your annual bonus may be more or less (and may equal zero). For your initial year, you must be actively employed prior to October 1 to be bonus eligible, and any such bonus will be prorated. Any annual bonus awarded to you shall be paid within two and a half months following the year to which the annual bonus relates and will be contingent upon your continued employment through the applicable payment date. You hereby acknowledge and agree that nothing contained herein confers upon you any right to an annual bonus in any year, and that whether the Company pays you an annual bonus and the amount of any such annual bonus will be determined by the Company in its sole discretion.

In connection with entering into this offer letter, following the commencement of your employment with the Company, the Company will recommend to the Board that it grant you an option to purchase **800,000** shares (subject to appropriate adjustment in the event of any stock

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dividend, stock split, combination or other similar recapitalization) of the Company's common stock (the "Stock Option") at a per-share exercise price equal to the fair market value of a share of the Company's common stock on the date of grant (as determined in accordance with the terms of the Company's equity award plan). Subject to your continued employment with the Company through the applicable vesting date, 25% of the total number of shares underlying the Stock Option will vest on the first anniversary of the applicable vesting commencement date and 1/48th of the total number of shares initially underlying the Stock Option will vest on each monthly anniversary thereafter. The Stock Option will otherwise be subject to the terms and conditions of the Company's 2021 Incentive Award Plan and a stock option agreement to be entered into between you and the Company. You will be eligible to receive future stock options and other equity awards in the discretion of the Board.

You will be eligible to participate in all of the employee benefits and benefit plans that the Company generally makes available to its regular full-time employees. You will be eligible for paid time off, vacation and/or paid sick leave in accordance with applicable law and Company policy. Further, you will be eligible to receive any benefits applicable to Sana employees of your job level under the terms of the Company's then-current change in control severance plan.

The Company requires that, as a full-time employee, you devote your full business time, attention, skill, and efforts to the tasks and duties of your position as assigned by the Company. If you wish to request consent to provide services (for any or no form of compensation) to any other person or business entity while employed by the Company, please discuss that with me in advance of accepting another position.

As a condition of employment, you will be required: (1) to sign and comply with an At-Will Employment Agreement, a copy of which has been sent to you with this offer, which, among other things, prohibits unauthorized use or disclosure of Company proprietary information; (2) to sign and return a satisfactory I-9 immigration form, which will be sent to you as part of your onboarding should you accept this offer, and provide sufficient documentation establishing your employment eligibility in the United States of America; and (3) to provide satisfactory proof of your identity as required by U.S. law.

As a further condition of employment, except to the extent prohibited by applicable federal, state or local laws, the Company requires that you be fully vaccinated against COVID-19, including receipt of a vaccine booster shot if recommended for you by the CDC, subject to certain exceptions. If you would like to request a reasonable accommodation, please contact your Recruiter to discuss the accommodation process before signing this agreement. Proof of your vaccination against COVID-19 must be provided to the Company no later than your first day of employment. By signing the offer letter, you are confirming no accommodation is requested or that an accommodation has been documented and signed that meets the needs of both parties.

As a further express condition of employment, you must consent to and satisfactorily pass (to the Company's satisfaction) a background check. You should not rely upon the terms of this offer letter until you have been informed in writing by the Company that you have successfully satisfied such background check. You will be contacted soon by the Company's third-party background check vendor, Accurate. Accurate will provide you with a disclosure of your rights under relevant federal and state law and request your authorization to perform a background check on you for the Company and provide the results of the background check to the Company.

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By signing below, you represent that your performance of services to the Company will not violate any duty which you may have to any other person or entity (such as a present or former employer), including obligations concerning providing services (whether or not competitive) to others, confidentiality of proprietary information and assignment of inventions, ideas, patents or copyrights, and you agree that you will not do anything in the performance of services hereunder that would violate any such duty.

Notwithstanding any of the above, your employment with the Company is “at will.” This means that it is not for any specified period of time and can be terminated by you or by the Company at any time, with or without advance notice, and for any or no particular reason or cause. It also means that your job duties, title and responsibility and reporting level, work schedule, compensation and benefits, as well as the Company’s personnel policies and procedures, may be changed with prospective effect, with or without notice, at any time in the sole discretion of the Company.

Without limiting the foregoing, if at any time other than during a Change in Control Period (as defined below) your employment with the Company is terminated by the Company without Cause (other than due to your death or disability) or you resign for Good Reason (each, as defined herein) and you deliver to the Company a general release of all claims against the Company and its affiliates in a form reasonably acceptable to the Company (a “Release”) that becomes effective and irrevocable within 60 days following such termination of employment, then you shall be entitled to receive (i) continuing payments of severance pay (less applicable withholding taxes) for a period of nine (9) months to be paid periodically in accordance with the Company’s normal payroll policies at a rate equal to the sum of your monthly base salary rate and one-twelfth of your target annual bonus, in each case as in effect immediately prior to your termination (but without taking into account any reduction of your base salary or target annual bonus that would constitute a breach of this letter), less applicable withholdings, with such installments to commence on the first payroll date following the date the Release becomes effective and irrevocable, with the first installment to include any amount that would have been paid had the Release been effective and irrevocable on your termination date and (ii) direct payment or reimbursement for premiums for continued health, vision and dental benefit coverage through COBRA for you, your spouse and dependents at the same level of coverage as in effect for you on the day immediately preceding the day of termination of employment for a period ending on the earlier of (a) nine months (9) after the date of termination of employment and (b) the date you are eligible to receive health, vision and dental benefits through a new employer.

For purposes of this offer letter, the term “Cause” means: (i) a willful act of dishonesty made by you in connection with your responsibilities as an employee; (ii) your conviction of, or plea of *nolo contendere* to, a felony or any crime involving fraud, embezzlement or a material violation of federal or state law by you, any of which that the Board reasonably determines in good faith has had or will have a material detrimental effect on the Company’s reputation or business; (iii) your willful and material unauthorized use or disclosure of any proprietary information or tradesecrets of the Company or any other party to whom you owe an obligation of nondisclosure as a result of your relationship with the Company; (iv) your willful material breach of any obligations under any written agreement or covenant with the Company; or (v) your continued substantial failure to perform your employment duties (other than as a result of your physical or mental incapacity). No termination for Cause under (iv) or (v) shall be effectuated until after you have received a written

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demand of performance from the CEO that specifically sets forth the factual basis for the CEO's determination that you have not substantially performed your duties and have failed to cure such non-performance to the CEO's reasonable satisfaction within thirty (30) business days after receiving such notice. For purposes of this definition, no act or failure to act shall be considered willful unless it is done in bad faith and without reasonable intent that the act or failure to act was in the best interest of the Company. Any act, or failure to act, based upon authority or instructions given to you pursuant to a resolution duly adopted by the CEO or based on the advice of counsel for the Company will be conclusively presumed to be done or omitted to be done by you in good faith and in the best interest of the Company.

For purposes of this offer letter, the term "Good Reason" means your resignation within 30 days following expiration of any Cure Period (as defined below) following the occurrence of one or more of the following without your written consent: (i) a material reduction in your base salary or target annual bonus; (ii) a material diminution of your title, duties, responsibilities or reporting lines; or (iii) a change in the location of your employment of more than 50 miles. No event will be considered Good Reason unless (a) you have given written notice to the Company of your intention to terminate your employment for Good Reason, describing the grounds for such action, no later than 90 days after the first occurrence of such circumstances, (b) you have provided the Company with at least 30 days in which to cure the circumstances (the "Cure Period"), and (c) if the Company is not successful in curing the circumstance, you end your employment within thirty days after the end of the Cure Period.

For purposes of this offer letter, the term "Change in Control" shall have the meaning ascribed such term in the Company's 2021 Incentive Award Plan, provided, that such event constitutes a "change in control event" within the meaning of Section 409A of the Internal Revenue Code of 1986, as amended (the "Code").

For purposes of this offer letter, the term "Change in Control Period" shall mean the period commencing three (3) months prior to a Change in Control and ending twelve (12) months after the Change in Control.

No amount deemed deferred compensation subject to Section 409A of the Code shall be payable pursuant to this offer letter unless your termination of employment constitutes a "separation from service" with the Company within the meaning of Section 409A of the Code, and the Department of Treasury regulations and other guidance promulgated thereunder. For purposes of Section 409A of the Code (including, without limitation, for purposes of Treasury Regulation Section 1.409A-2(b)(2)(iii)), your right to receive any installment payments under this offer letter shall be treated as a right to receive a series of separate payments and, accordingly, each such installment payment shall at all times be considered a separate and distinct payment. To the extent that any reimbursements payable pursuant to this offer letter are subject to the provisions of Section 409A of the Code, any such reimbursements payable to you pursuant to this offer letter shall be paid to you no later than December 31 of the year following the year in which the expense was incurred, the amount of expenses reimbursed in one year shall not affect the amount eligible for reimbursement in any subsequent year, and your right to reimbursement under this offer letter will not be subject to liquidation or exchange for another benefit.

You are not required to seek other employment or otherwise mitigate the value of any severance benefits contemplated by this offer letter, nor will any such benefits be reduced by any earnings or

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benefits that you may receive from any other source, except as otherwise expressly set forth above with respect to continued group life, health, vision and dental benefits.

In addition to any indemnification provided by the Company's organizational documents, the Company will enter into an indemnification agreement with you as a senior executive in the form used for other senior executives.

If you accept this offer, this letter and the At-Will Employment Agreement shall constitute the complete agreement between you and Company with respect to the terms and conditions of your employment. Any prior or contemporaneous representations (whether oral or written) not contained in this letter or the At-Will Employment Agreement or contrary to those contained in this letter or the At-Will Employment Agreement, that may have been made to you are expressly cancelled and superseded by this offer.

This offer letter shall be interpreted and construed in accordance with the laws of Washington without regard to any conflicts of laws principles. Although other terms and conditions of your employment may change in the future, the at-will nature of your employment may not be changed, except in a subsequent letter or written agreement, signed by you and the CEO of the Company.

*(Signature Page Follows)*

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Please sign and date this letter and the At-Will Employment Agreement, and submit it through DocuSign by **September 9, 2022** if you wish to accept employment at the Company under the terms described above, after which time this offer of employment will expire. If you accept our offer, we would like you to commence your employment with us as soon as practicable.

This offer letter may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same letter. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, e.g., [www.docusign.com](http://www.docusign.com)) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

If you have any questions, regarding this letter or employment with the Company, please feel free to contact your recruiter. We look forward to your favorable reply and to a productive and enjoyable work relationship.

Sincerely,

**SANA BIOTECHNOLOGY, INC.**

/s/ Robin Andrulevich

Name: Robin Andrulevich

Title: Chief People Officer

Date: September 6, 2022

**Accepted by:**

/s/ Bernard Cassidy

\_\_\_\_\_

Bernard Cassidy

September 8, 2022

\_\_\_\_\_

Date

**SANA BIOTECHNOLOGY, INC.**  
**2021 EMPLOYEE STOCK PURCHASE PLAN**  
**AMENDMENT**

This Amendment No. 1 to the 2021 Employee Stock Purchase Plan (this “Amendment”) is made by Sana Biotechnology, Inc. (the “Company”) as of October 27, 2022 (the “Effective Date”). Capitalized terms used herein and not otherwise defined shall have the meaning ascribed thereto in the 2021 Employee Stock Purchase Plan (as amended, the “Plan”).

WHEREAS, pursuant to Section 7.5 of the Plan, the Board may, in its sole discretion, amend, suspend or terminate the Plan at any time and from time to time, and shall obtain stockholder approval of any Plan amendment to the extent necessary to comply with Section 423 of the Code (or any successor rule or provision), with respect to the Section 423 Component, or any other applicable law, regulation or stock exchange rule;

WHEREAS, the Board has determined that the actions set forth in this Amendment do not require the approval of the Company’s stockholders; and

WHEREAS, the Board has determined that it is in the best interest of the Company to amend the Plan as set forth in this Amendment.

NOW, THEREFORE, in accordance with the foregoing, the Plan is amended as follows:

1. Section 4.3(c) of the Plan is hereby amended and restated in its entirety to read as follows:

“(c) Intentionally omitted.”

2. Except as modified by this Amendment, all terms and provisions of the Plan shall remain in full force and effect.

**IN WITNESS WHEREOF**, the Company has executed this Amendment as of the Effective Date.

**Sana Biotechnology, Inc.**

/s/ Bernard J. Cassidy\_\_\_\_\_

By: Bernard J. Cassidy

Its: Executive Vice President, General Counsel and Corporate Secretary





**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, 2022 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 2, 2022

By: \_\_\_\_\_ /s/ Steven D. Harr, M.D.  
Steven D. Harr, M.D.  
President and Chief Executive 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, 2022 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 2, 2022

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