UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2021

OR

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

For the transition period from to

Commission File Number: 001-38841

Precision BioSciences, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**20-4206017**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
302 East Pettigrew St., Suite A-100 Durham, North Carolina	**27701**
(Address of principal executive offices)	**(Zip Code)**

(919) 314-5512
(Registrant's telephone number, including area code)

N/A
(Former name, former address and former fiscal year, if changed since last report)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.000005 per share	DTIL	The Nasdaq Global Select Market

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

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

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

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

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

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

As of May 6, 2021, the registrant had 57,480,326 shares of common stock, $0.000005 par value per share, outstanding.

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FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements other than statements of present and historical facts contained in this Quarterly Report on Form 10-Q, including without limitation, statements regarding our future results of operations and financial position, business strategy and approach, including related results, prospective products, planned preclinical or greenhouse studies and clinical or field trials, the status and results of our preclinical and clinical studies, expected release of interim data, expectations regarding our allogeneic chimeric antigen receptor T cell immunotherapy product candidates, expectations regarding the use and effects of ARCUS, including in connection with *in vivo* genome editing, potential new partnerships or alternative opportunities for our product candidates, capabilities of our manufacturing facility, regulatory approvals, research and development costs, timing, expected results and likelihood of success, plans and objectives of management for future operations, as well as the impact of the COVID-19 pandemic may be forward-looking statements. Without limiting the foregoing, in some cases, you can identify forward-looking statements by terms such as "aim," "may," "will," "should," "expect," "exploring," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential," "seeks," or "continue" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. No forward-looking statement is a guarantee of future results, performance, or achievements, and one should avoid placing undue reliance on such statements.

Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to us. Such beliefs and assumptions may or may not prove to be correct. Additionally, such forward-looking statements are subject to a number of known and unknown risks, uncertainties and assumptions, and actual results may differ materially from those expressed or implied in the forward-looking statements due to various factors, including, but not limited to, those identified in Part I. Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations" and Part II. Item 1A. "Risk Factors." These risks and uncertainties include, but are not limited to:

- our ability to become profitable;
- our ability to procure sufficient funding and requirements under our current debt instruments and effects of restrictions thereunder;
- risks associated with raising additional capital;
- our operating expenses and our ability to predict what those expenses will be;
- our limited operating history;
- the success of our programs and product candidates in which we expend our resources;
- our dependence on our ARCUS technology;
- the risk that other genome-editing technologies may provide significant advantages over our ARCUS technology;
- the initiation, cost, timing, progress, achievement of milestones and results of research and development activities, preclinical or greenhouse studies and clinical or field trials;
- public perception about genome editing technology and its applications;
- competition in the genome editing, biopharmaceutical, biotechnology and agricultural biotechnology fields;
- our or our collaborators' ability to identify, develop and commercialize product candidates;
- pending and potential liability lawsuits and penalties against us or our collaborators related to our technology and our product candidates;
- the U.S. and foreign regulatory landscape applicable to our and our collaborators' development of product candidates;
- our or our collaborators' ability to obtain and maintain regulatory approval of our product candidates, and any related restrictions, limitations and/or warnings in the label of an approved product candidate;

- our or our collaborators' ability to advance product candidates into, and successfully design, implement and complete, clinical or field trials;
- potential manufacturing problems associated with the development or commercialization of any of our product candidates;
- our ability to obtain an adequate supply of T cells from qualified donors;
- our ability to achieve our anticipated operating efficiencies at our manufacturing facility;
- delays or difficulties in our and our collaborators' ability to enroll patients;
- changes in interim "top-line" data that we announce or publish;
- if our product candidates do not work as intended or cause undesirable side effects;
- risks associated with applicable healthcare, data privacy and security regulations and our compliance therewith;
- the rate and degree of market acceptance of any of our product candidates;
- the success of our existing collaboration agreements, and our ability to enter into new collaboration arrangements;
- our current and future relationships with third parties including suppliers and manufacturers;
- our ability to obtain and maintain intellectual property protection for our technology and any of our product candidates;
- potential litigation relating to infringement or misappropriation of intellectual property rights;
- our ability to effectively manage the growth of our operations;
- our ability to attract, retain, and motivate key scientific and management personnel;
- market and economic conditions;
- effects of system failures and security breaches;
- effects of natural and manmade disasters, public health emergencies and other natural catastrophic events;
- effects of COVID-19, or any pandemic, epidemic, or outbreak of an infectious disease;
- insurance expenses and exposure to uninsured liabilities;
- effects of tax rules; and
- risks related to ownership of our common stock, including fluctuations in our stock price.

Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties.

You should read this Quarterly Report on Form 10-Q and the documents that we reference herein completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements. All forward-looking statements contained herein speak only as of the date of this Quarterly Report on Form 10-Q. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

As used in this Quarterly Report on Form 10-Q, unless otherwise stated or the context requires otherwise, references to "Precision," the "Company," "we," "us," and "our," refer to Precision BioSciences, Inc. and its subsidiaries on a consolidated basis.

RISK FACTOR SUMMARY

Our business is subject to numerous risks and uncertainties, including those described in Part II. Item 1A. “Risk Factors” in this Quarterly Report on Form 10-Q. You should carefully consider these risks and uncertainties when investing in our common stock. Some of the principal risks and uncertainties include the following.

- *We have incurred significant operating losses since our inception and expect to continue to incur losses for the foreseeable future. We have never been profitable, and may never achieve or maintain profitability.*
- *We will need substantial additional funding, and if we are unable to raise a sufficient amount of capital when needed on acceptable terms, or at all, we may be forced to delay, reduce or eliminate some or all of our research programs, product development activities and commercialization efforts.*
- *We have a limited operating history, which makes it difficult to evaluate our current business and future prospects and may increase the risk of your investment.*
- *ARCUS is a novel technology, making it difficult to predict the time, cost and potential success of product candidate development. We have not yet been able to assess the safety and efficacy of most of our product candidates in humans, and have only limited safety and efficacy information in humans to date regarding one of our product candidates.*
- *We are heavily dependent on the successful development and translation of ARCUS, and due to the early stages of our product development operations, we cannot give any assurance that any product candidates will be successfully developed and commercialized.*
- *Adverse public perception of genome editing may negatively impact the developmental progress or commercial success of products that we develop alone or with collaborators.*
- *We face significant competition in industries experiencing rapid technological change, and there is a possibility that our competitors may achieve regulatory approval before us or develop product candidates or treatments that are safer or more effective than ours, which may harm our financial condition and our ability to successfully market or commercialize any of our product candidates.*
- *Our future profitability, if any, depends in part on our and our collaborators’ ability to penetrate global markets, where we would be subject to additional regulatory burdens and other risks and uncertainties associated with international operations that could materially adversely affect our business.*
- *Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any products that we develop alone or with collaborators.*
- *The regulatory landscape that will apply to development of therapeutic product candidates by us or our collaborators is rigorous, complex, uncertain and subject to change, which could result in delays or termination of development of such product candidates or unexpected costs in obtaining regulatory approvals.*
- *Clinical trials are difficult to design and implement, expensive, time-consuming and involve an uncertain outcome, and the inability to successfully and timely conduct clinical trials and obtain regulatory approval for our product candidates would substantially harm our business.*
- *Even if we obtain regulatory approval for any products that we develop alone or with collaborators, such products will remain subject to ongoing regulatory requirements, which may result in significant additional expense.*
- *Even if any product we develop alone or with collaborators receives marketing approval, such product may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success.*
- *The ongoing novel coronavirus disease, COVID-19, has impacted our business and any other pandemic, epidemic or outbreak of an infectious disease may materially and adversely impact our business, including our preclinical studies and clinical trials.*

Item 1. Financial Statements.

PRECISION BIOSCIENCES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)
(Unaudited)

	March 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 193,460	$ 89,798
Accounts receivable	19,263	10,000
Prepaid expenses	6,381	5,762
Other current assets	35	4
Total current assets	219,139	105,564
Property, equipment, and software—net	33,887	35,090
Intangible assets—net	1,358	1,373
Right-of-use assets	6,120	6,410
Other assets	1,812	1,721
Total assets	$ 262,316	$ 150,158
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 445	$ 792
Accrued compensation	2,634	5,745
Accrued clinical and research and development expenses	3,598	3,269
Deferred revenue	53,094	30,236
Lease liabilities	1,996	1,933
Other current liabilities	2,030	854
Total current liabilities	63,797	42,829
Deferred revenue	131,243	53,926
Lease liabilities	8,062	8,586
Other noncurrent liabilities	392	392
Total liabilities	203,494	105,733
Commitments and contingencies (Note 4)		
Stockholders' equity:		
Preferred stock, $0.0001 par value— 10,000,000 shares authorized as of March 31, 2021 and December 31, 2020; no shares issued and outstanding as of March 31, 2021 and December 31, 2020	—	—
Common stock; $0.000005 par value— 200,000,000 shares authorized as of March 31, 2021 and December 31, 2020; 58,032,901 shares issued and 57,222,429 shares outstanding as of March 31, 2021; 53,503,124 shares issued and 52,692,652 shares outstanding as of December 31, 2020	—	—
Additional paid-in capital	364,536	331,450
Accumulated deficit	(304,762)	(286,073)
Treasury stock	(952)	(952)
Total stockholders' equity	58,822	44,425
Total liabilities and stockholders' equity	$ 262,316	$ 150,158

See notes to condensed consolidated financial statements

PRECISION BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share amounts)
(Unaudited)

	For the Three Months Ended March 31,	
	2021	2020
Revenue	$ 16,349	$ 6,998
Operating expenses		
Research and development	25,593	24,879
General and administrative	9,498	9,615
Total operating expenses	35,091	34,494
Loss from operations	(18,742)	(27,496)
Other income:		
Interest income	53	660
Net loss and net loss attributable to common stockholders	$ (18,689)	$ (26,836)
Net loss per share attributable to common stockholders-basic and diluted	$ (0.33)	$ (0.52)
Weighted average shares of common stock outstanding-basic and diluted	56,625,024	51,312,770

See notes to condensed consolidated financial statements

PRECISION BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(In thousands, except share amounts)
(Unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Treasury Stock	Total Stockholder's Equity
	Shares	Amount				
Balance- January 1, 2020	51,965,708	$ —	$ 316,333	$ (177,067)	$ (952)	$ 138,314
Stock option exercises	244,999	—	212	—	—	212
Issuance of common stock under employee stock purchase plan	42,620	—	239	—	—	239
Share-based compensation expense	—	—	3,105	—	—	3,105
Net loss	—	—	—	(26,836)	—	(26,836)
Balance- March 31, 2020	52,253,327	$ —	$ 319,889	$ (203,903)	$ (952)	$ 115,034
Balance- January 1, 2021	53,503,124	$ —	$ 331,450	$ (286,073)	$ (952)	$ 44,425
Stock option exercises	676,791	—	1,297	—	—	1,297
Issuance of common stock under employee stock purchase plan	90,796	—	418	—	—	418
Share-based compensation expense	—	—	3,632	—	—	3,632
Issuance of common stock to collaboration partners	3,762,190	—	27,739	—	—	27,739
Net loss	—	—	—	(18,689)	—	(18,689)
Balance- March 31, 2021	58,032,901	$ —	$ 364,536	$ (304,762)	$ (952)	$ 58,822

See notes to condensed consolidated financial statements

PRECISION BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	For the Three Months Ended March 31,	
	2021	2020
Cash flows from operating activities:		
Net loss	$ (18,689)	$ (26,836)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	2,176	2,155
Share-based compensation	3,632	3,105
Loss on disposal of property, equipment, and software	23	—
Amortization of right-of-use assets	290	235
Changes in operating assets and liabilities:		
Prepaid expenses	(619)	1,635
Accounts receivable	(9,263)	(2,894)
Other assets and other current assets	(6)	1,411
Accounts payable	221	(266)
Other current liabilities	(2,146)	(916)
Deferred revenue	92,914	(3,139)
Lease liabilities and right-of-use assets	(461)	(400)
Net cash provided by (used in) operating activities	68,072	(25,910)
Cash flows from investing activities:		
Purchases of property, equipment and software	(1,125)	(1,103)
Net cash used in investing activities	(1,125)	(1,103)
Cash flows from financing activities:		
Proceeds from stock option exercises	1,297	212
Proceeds from employee stock purchase plan	418	239
Deferred offering costs	—	(137)
Proceeds from issuance of common stock to collaboration partners	35,000	—
Net cash provided by financing activities	36,715	314
Net increase (decrease) in cash and cash equivalents	103,662	(26,699)
Cash and cash equivalents—beginning of period	89,798	180,886
Cash and cash equivalents —end of period	$ 193,460	$ 154,187
Supplemental disclosures of noncash financing and investing activities:		
Property, equipment and software additions included in accounts payable, accrued expenses and other current liabilities	$ 637	$ 651
Deferred offering costs included in accounts payable, accrued expenses and other current liabilities	$ —	$ 66

See notes to condensed consolidated financial statements

NOTE 1: DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Description of Business

Precision BioSciences, Inc. (the "Company") was incorporated on January 26, 2006 under the laws of the State of Delaware and is based in Durham, North Carolina. The Company is dedicated to improving life through the application of its pioneering, proprietary ARCUS genome editing platform to treat human diseases and create healthy and sustainable food and agricultural solutions. The Company is actively developing product candidates through two reportable segments: Therapeutics and Food. The Therapeutics segment is focused on allogeneic chimeric antigen receptor T ("CAR T") cell immunotherapy and *in vivo* gene correction. The Food segment focuses on applying ARCUS to develop food and nutrition products through collaboration agreements with consumer-facing companies.

The Company's 100% owned subsidiary, Precision PlantSciences, Inc., was incorporated on January 4, 2012. Precision PlantSciences, Inc. amended its certificate of incorporation on January 16, 2018 to change its name to Elo Life Systems, Inc. Elo Life Systems Australia Pty Ltd was incorporated on May 29, 2018 as a 100% owned subsidiary of Elo Life Systems, Inc. Additionally, the Company's 100% owned subsidiary Precision BioSciences UK Limited was incorporated on June 17, 2019. The accompanying condensed consolidated financial statements include the accounts of the Company and its subsidiaries. Intercompany balances and transactions have been eliminated in consolidation.

Since its inception, the Company has devoted substantially all of its efforts to research and development activities, recruiting skilled personnel, developing manufacturing processes, establishing its intellectual property portfolio and providing general and administrative support for these operations. The Company is subject to a number of risks similar to those of other companies conducting high-risk, early-stage research and development of product candidates. Principal among these risks are dependence on key individuals and intellectual property, competition from other products and companies, and the technical risks associated with the successful research, development and clinical manufacturing of its product candidates. The Company's success is dependent upon its ability to continue to raise additional capital in order to fund ongoing research and development, obtain regulatory approval of its products, successfully commercialize its products, generate revenue, meet its obligations, and, ultimately, attain profitable operations.

Management believes that existing cash and cash equivalents at the time these financial statements were issued, expected operational receipts and available credit will allow the Company to continue its operations into 2023. In the absence of a significant source of recurring revenue, the continued viability of the Company beyond that point is dependent on its ability to continue to raise additional capital to finance its operations. There can be no assurance that the Company will be able to obtain sufficient capital to cover its costs on acceptable terms, if at all.

Unaudited Interim Financial Information

The accompanying unaudited condensed consolidated financial statements and notes have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC"). Certain information and note disclosures normally included in the annual financial statements, prepared in accordance with accounting principles generally accepted in the U.S. ("GAAP"), have been condensed or omitted pursuant to those rules and regulations. These unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and the notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2020, filed with the SEC on March 18, 2021.

The unaudited condensed consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements. In the opinion of management, all adjustments, consisting only of normal recurring adjustments necessary for a fair presentation of the Company's condensed consolidated financial position as of March 31, 2021 and condensed consolidated results of operations for the three months ended March 31, 2021 and 2020 and the condensed consolidated cash flows for the three months ended March 31, 2021 and 2020, have been made. The Company's condensed consolidated results of operations for the three months ended March 31, 2021 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2021.

Summary of Significant Accounting Policies

Revenue Recognition for Contracts with Customers

The Company's revenues are generated primarily through collaborative research, license, development and commercialization agreements.

ASC 606 applies to all contracts with customers, except for contracts that are within the scope of other standards. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

At contract inception, once the contract is determined to be within the scope of ASC 606, the Company evaluates the performance obligations promised in the contract that are based on goods and services that will be transferred to the customer and determines whether those obligations are both (i) capable of being distinct and (ii) distinct in the context of the contract. Goods or services that meet these criteria are considered distinct performance obligations. If both these criteria are not met, the goods and services are combined into a single performance obligation. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. Arrangements that include rights to additional goods or services that are exercisable at a customer's discretion are generally considered options. The Company assesses if these options provide a material right to the customer and if so, these options are considered performance obligations. The exercise of a material right is accounted for as a contract modification for accounting purposes.

The Company recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) each performance obligation is satisfied at a point in time or over time, and if over time this is based on the use of an output or input method. For the three months ended March 31, 2021, the Company recorded cumulative catch up adjustments that increased revenue recognition by $2.9 million, in addition to a contract liability adjustment, for changes in total estimated effort to be incurred in the future to satisfy the performance obligation and changes to the transaction price related to variable consideration for development milestones that were constrained in prior periods. During the three months ended March 31, 2021, the Company recorded $11.0 million in revenue that was included in deferred revenue as of December 31, 2020.

Invoices issued as stipulated in contracts prior to revenue recognition are recorded as deferred revenue. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue within current liabilities in the accompanying condensed consolidated balance sheets. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as noncurrent deferred revenue. Amounts recognized as revenue, but not yet invoiced are generally recognized as contract assets in the other current assets line item in the accompanying condensed consolidated balance sheets.

Milestone Payments – If an arrangement includes development and regulatory milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's or the licensee's control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received and therefore revenue recognized is constrained as management is unable to assert that a reversal of revenue would not be probable. The transaction price is then allocated to each performance obligation on a relative standalone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint, and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration revenues and earnings in the period of adjustment.

Royalties – For arrangements that include sales-based royalties, including milestone payments based on a level of sales, which are the result of a customer-vendor relationship and for which the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation linked to some or all of the royalty has been satisfied or partially satisfied. To date, the Company has not recognized any royalty revenue resulting from any of its licensing arrangements.

Significant Financing Component – In determining the transaction price, the Company adjusts consideration for the effects of the time value of money if the timing of payments provides the Company with a significant benefit of financing. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between

payment by the licensees and the transfer of the promised goods or services to the licensees will be one year or less. The Company assessed each of its revenue arrangements in order to determine whether a significant financing component exists and concluded that a significant financing component does not exist in any of its arrangements.

Collaborative Arrangements – The Company has entered into collaboration agreements, which are within the scope of ASC 606, to discover, develop, manufacture and commercialize product candidates. The terms of these agreements typically contain multiple promises or obligations, which may include: (1) licenses, or options to obtain licenses, to use the Company's technology, (2) research and development activities to be performed on behalf of the collaboration partner, and (3) in certain cases, services in connection with the manufacturing of preclinical and clinical material. Payments the Company receives under these arrangements typically include one or more of the following: non-refundable, upfront license fees; option exercise fees; funding of research and/or development efforts; clinical and development, regulatory, and sales milestone payments; and royalties on future product sales.

The Company analyzes its collaboration arrangements to assess whether the collaboration agreements are within the scope of accounting standards codification ("ASC") ASC 808, Collaborative Arrangements ("ASC 808") to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of ASC 808 that contain multiple elements, the Company first determines which elements of the collaboration are deemed to be within the scope of ASC 808 and those that are more reflective of a vendor-customer relationship and, therefore, are within the scope of ASC 606. For elements of collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently, generally by analogy to ASC 606. For those elements of the arrangement that are accounted for pursuant to ASC 606, the Company applies the five-step model described above.

For additional discussion of accounting for collaboration revenues, see Note 8, "Collaboration and License Agreements."

NOTE 2: STOCKHOLDERS' EQUITY

Capital Structure

On April 1, 2019, the Company filed an amendment to its amended and restated certificate of incorporation pursuant to which, among other things, the Company increased its authorized shares to 210,000,000 shares of capital stock, of which 200,000,000 shares were designated as $0.000005 par value common stock and 10,000,000 shares were designated as $0.0001 par value preferred stock.

NOTE 3: SHARE-BASED COMPENSATION

The Company previously granted stock options under its 2006 Stock Incentive Plan (the "2006 Plan") and its 2015 Stock Incentive Plan (the "2015 Plan"). As of March 31, 2021 there were 4,307,433 stock options outstanding under the 2006 Plan and 2015 Plan and no remaining stock options available to be granted under such plans.

On March 12, 2019, the Company's board of directors adopted, and, on March 14, 2019 the Company's stockholders approved, the Precision BioSciences, Inc. 2019 Incentive Award Plan ("2019 Plan") and the 2019 Employee Stock Purchase Plan ("2019 ESPP"), both of which became effective on March 27, 2019.

The 2019 Plan provides for the grant of incentive stock options, non-qualified stock options, stock appreciation rights, restricted stock, restricted stock units and other share-based awards. The number of shares available for issuance under the 2019 Plan initially equaled 4,750,000 shares of common stock. The 2019 Plan provides for an annual increase to the number of shares of common stock available for issuance on the first day of each calendar year beginning January 1, 2020 and ending on and including January 1, 2029 by an amount equal to the lesser of (i) 4% of the aggregate number of shares of common stock outstanding on the final day of the immediately preceding calendar year and (ii) such smaller number of shares of common stock as determined by the board of directors. As of March 31, 2021, the aggregate number of shares available for issuance under the 2019 Plan has been increased by 4,153,915 pursuant to this provision. Any shares that are subject to awards outstanding under the Company's 2006 Plan and 2015 Plan as of the effective date of the 2019 Plan that expire, lapse, or are terminated, exchanged for cash, surrendered, repurchased, or canceled without having been fully exercised or forfeited, to the extent so unused, will become available for award grants under the 2019 Plan. As of March 31, 2021, 4,105,617 shares were available to be issued under the 2019 Plan. The 2019 Plan had 5,495,916 stock options outstanding as of March 31, 2021.

Up to 525,000 shares of the Company's common stock were initially reserved for issuance under the 2019 ESPP. The 2019 ESPP provides for an annual increase to the number of shares available for issuance on the first day of each calendar year beginning January 1, 2020 and ending on and including January 1, 2029 by an amount equal to the lesser of (i) 1% of the shares outstanding on the final day of the immediately preceding calendar year and (ii) such smaller number of shares as is determined by our board of directors. As of March 31, 2021, the aggregate number of shares available for issuance under the 2019 ESPP has been increased by 1,038,478 shares pursuant to this provision. No more than 5,250,000 shares of our common stock may be issued under our 2019 ESPP. The purchase price of the shares under the 2019 ESPP, in the absence of a contrary designation, will be 85% of the lower of the fair market value of our common stock on the first trading day of the offering period or on the purchase date. As of March 31, 2021, the Company had issued 217,024 shares under the 2019 ESPP. As of March 31, 2021, 1,346,454 shares were available to be issued under the 2019 ESPP. The Company recognized share-based compensation expense related to the ESPP of less than $0.1 million during each of the three months ended March 31, 2021 and 2020.

The Company recorded employee and nonemployee share-based compensation expense as follows (in thousands):

	Three Months Ended March 31,	
	2021	2020
Employee	$ 3,278	$ 2,929
Nonemployee	354	176
	$ 3,632	$ 3,105

Share-based compensation expense is included in the following line items in the condensed consolidated statements of operations (in thousands):

	Three Months Ended March 31,	
	2021	2020
Research and development	$ 2,082	$ 1,855
General and administrative	1,550	1,250
	$ 3,632	$ 3,105

Determining the appropriate fair value model to measure the fair value of the stock option grants on the date of grant and the related assumptions requires judgment. The fair value of each stock option grant is estimated using a Black-Scholes option-pricing model on the date of grant as follows:

	Three Months Ended March 31,
	2021
Estimated dividend yield	0.00%
Weighted-average expected stock price volatility	73.69%
Weighted-average risk-free interest rate	0.66%
Expected life of options (in years)	6.43
Weighted-average fair value per option	8.32

The expected volatility rates are estimated based on the actual volatility of comparable public companies over the expected term. The expected term represents the average time that stock options that vest are expected to be outstanding. The Company does not have sufficient history of exercising stock options to estimate the expected term of employee stock options and thus utilizes a weighted value considering actual history and estimated expected term based on the midpoint of final vest date and expiration date. The risk-free rate is based on the United States Treasury yield curve during the expected life of the option.

The following table summarizes activity in the Company's stock option plans for the three months ended March 31, 2021:

	Outstanding Option Shares	Weighted-Average Exercise Price
Balance as of January 1, 2020	10,544,270	$ 7.88
Granted	106,186	12.66
Exercised	(676,791)	1.92
Forfeited/canceled	(170,316)	10.92
Balance as of March 31, 2021	9,803,349	$ 8.29

The intrinsic value of stock options exercised was $6.8 million and $2.1 million during the three months ended March 31, 2021 and 2020, respectively.

There was approximately $27.1 million of total unrecognized compensation cost related to unvested stock options as of March 31, 2021, which is expected to be recognized over a weighted-average period of 2.0 years.

NOTE 4: COMMITMENTS AND CONTINGENCIES

Litigation

The Company is not currently subject to any material legal proceedings.

COVID-19 Pandemic

In March 2020, the World Health Organization designated the outbreak of the novel strain of coronavirus known as COVID-19 as a global pandemic. The Company has taken steps in line with guidance from the U.S. Centers for Disease Control and Prevention ("CDC") and the State of North Carolina to protect the health and safety of its employees and the community.

The Company is working closely with its clinical sites, physician partners and the patient community to monitor and manage the ongoing impact of the COVID-19 pandemic. The Company remains committed to its clinical programs and development plans, however, disruptions, competing resource demands and safety concerns caused by the COVID-19 pandemic have caused delays in the Company's clinical trial site activation and impacted its ability to enroll patients. The Company may also experience other difficulties, disruptions or delays in conducting preclinical studies, initiating, enrolling, conducting or completing its planned and ongoing clinical trials or supply chain disruptions, and the Company may incur other unforeseen costs as a result. While the extent to which COVID-19 may continue to impact the Company's future results will depend on future developments, the pandemic and associated economic impacts could result in a material impact to the Company's future financial condition, results of operations and cash flows.

Leases

The Company has operating leases for real estate in North Carolina and does not have any finance leases.

Many of the Company's leases contain options to renew and extend lease terms and options to terminate leases early. Reflected in the right-of-use asset and lease liabilities on the Company's condensed consolidated balance sheet are the periods provided by renewal and extension options that the Company is reasonably certain to exercise, as well as the periods provided by termination options that the Company is reasonably certain to not exercise.

The Company has existing leases that include variable lease payments that are not included in the right-of-use asset and lease liabilities and are reflected as an expense in the period incurred. Such payments primarily include common area maintenance charges and fluctuations in rent payments that are driven by factors such as future changes in an index (e.g. the Consumer Price Index).

The Company has existing leases in which the non-lease components (e.g., common area maintenance, consumables, etc.) are paid separately from rent based on actual costs incurred and therefore are not included in the right-of-use assets and lease liabilities but rather reflected as an expense in the period incurred.

The elements of lease expense were as follows:

(in thousands)	Three Months Ended March 31, 2021
Lease Cost	
Operating lease cost	$ 491
Short-term lease cost	87
Variable lease cost	236
Total Lease Cost	$ 814
Other Information	
Operating cash flows used for operating leases	665
Operating Leases	
Weighted average remaining lease term (in years)	4.5
Operating Leases	
Weighted average discount rate	7.9%

Future lease payments under non-cancelable leases with terms of greater than one year as of March 31, 2021, were as follows:

(in thousands)	March 31, 2021
2021 (excluding the 3 months ended March 31, 2021)	$ 2,022
2022	2,769
2023	2,848
2024	2,134
2025	1,086
2026 and beyond	1,108
Total lease payments	11,967
Less: imputed interest	1,909
Total operating lease liabilities	$ 10,058

Supply Agreements

The Company enters into contracts in the normal course of business with contract manufacturing organizations (“CMOs”) for the manufacture of clinical trial materials and contract research organizations (“CROs”) for clinical trial services. These agreements provide for termination at the request of either party with less than one-year notice and are, therefore, cancelable contracts and, if canceled, are not anticipated to have a material effect on the condensed consolidated financial condition, results of operations, or cash flows of the Company.

NOTE 5: DEBT

In May 2019, the Company entered into a loan and security agreement with Pacific Western Bank (“PWB”), as subsequently amended (the “Pacific Western Loan”) pursuant to which the Company may request advances on a revolving line of credit of up to an aggregate principal of $30.0 million (the “Revolving Line”).

The Pacific Western Loan matures on June 23, 2023. All outstanding principal amounts are due on the maturity date. The Company must also maintain an aggregate balance of unrestricted cash at Bank (not including amounts in certain specified accounts) equal to or greater than $10.0 million. The interest rate under the Pacific Western Loan is a variable annual rate equal to the greater of (a) 2.75% above the Prime Rate (as defined in the Pacific Western Loan), or (b) 6.00%.

There have been no borrowings under the Pacific Western Loan as of the date of this Quarterly Report on Form 10-Q. The Company was in compliance with its financial covenants under the Pacific Western Loan as of March 31, 2021.

NOTE 6: INCOME TAXES

The Company estimates an annual effective tax rate of 0% for the year ending December 31, 2021 as the Company incurred losses for the three months ended March 31, 2021 and is forecasting additional losses through the remainder of fiscal year ending December 31, 2021, resulting in an estimated net loss for both financial statement and tax purposes for the year ending December 31, 2021. Therefore, no federal or state income taxes are expected and none have been recorded at this time. Income taxes have been accounted for using the liability method in accordance with ASC 740.

Due to the Company's history of losses since inception, there is not enough evidence at this time to support that the Company will generate future income of a sufficient amount and nature to utilize the benefits of its net deferred tax assets. Accordingly, the deferred tax assets have been reduced by a full valuation allowance, since the Company does not currently believe that realization of its deferred tax assets is more likely than not.

As of March 31, 2021, the Company had no unrecognized income tax benefits that would reduce the Company’s effective tax rate if recognized.

NOTE 7: FAIR VALUE MEASUREMENTS

The carrying amounts of the Company’s financial instruments, including accounts receivable, accounts payable, and accrued expenses and other current liabilities, approximate their respective fair values due to their short-term nature. The Company uses a three-tier fair value hierarchy to classify and disclose all assets and liabilities measured at fair value on a recurring basis and to minimize the use of unobservable inputs when determining their fair value. The three tiers are defined as follows:

Level 1—Observable inputs based on unadjusted quoted prices in active markets for identical assets or liabilities

Level 2—Inputs, other than quoted prices in active markets, that are observable either directly or indirectly

Level 3—Unobservable inputs for which there is little or no market date, which require the Company to develop its own assumptions

The Company classifies investments in money market funds within Level 1 as the prices are available from quoted prices in active markets. Investments in repurchase agreements are classified within Level 2 as these instruments are valued using observable market inputs including reported trades, broker/dealer quotes, bids and/or offers.

As of March 31, 2021, the Company held cash equivalents which are composed of money market funds and repurchase agreements that were purchased through repurchase intermediary banks and collateralized by deposits in the form of government securities and obligations. As of December 31, 2020, the Company held an insignificant amount of cash equivalents.

The following represents assets measured at fair value on a recurring basis by the Company (in thousands):

March 31, 2021	Fair Value	Level 1	Level 2	Level 3
Assets:				
Money market funds	$ 18	$ 18	$ —	$ —
Repurchase agreements	45,000	—	45,000	—
	$ 45,018	$ 18	$ 45,000	$ —

December 31, 2020	Fair Value	Level 1	Level 2	Level 3
Assets:				
Money market funds	$ 10	$ 10	$ —	$ —
Repurchase agreements	$ —	—	$ —	—
	$ 10	$ 10	$ —	$ —

NOTE 8: COLLABORATION AND LICENSE AGREEMENTS

Development and Commercial License Agreement with Servier

On February 24, 2016, the Company entered into a development and commercial license agreement, as subsequently amended, with predecessor entities to Servier. This agreement established a collaboration between the Company and Servier to develop allogeneic CAR T cell therapies for up to six unique antigen targets selected by Servier. Servier selected one target at the agreement's inception and, in 2020, selected two additional hematological cancer targets beyond CD19 and two new solid tumor targets. The Company granted Servier a development license and agreed to perform early-stage R&D on the selected targets and develop the resulting therapeutic product candidates through Phase 1 clinical trials and manufacture clinical trial material for use in Phase 2 clinical trials.

The Company recognizes revenue from the upfront payment of $105.0 million and variable consideration related to development milestones achieved on an input method in the form of research effort relative to expected research effort at the completion of the performance obligation, which is based on the actual time of R&D activities performed relative to expected time to be incurred in the future to satisfy the performance obligation. Management evaluates and adjusts the total expected research effort for the performance obligation on a quarterly basis based upon actual research accomplishments and the probability of continuing research efforts in the future. The transfer of control occurs over this time period and, in management's judgment, is the best measure of progress towards satisfying the performance obligation.

As further discussed in Note 10, Subsequent Events, on April 9, 2021, the Company entered into a Program Purchase Agreement (the "Program Purchase Agreement") with Servier, pursuant to which the Company terminated the development and commercial license agreement, as amended ("the Servier Agreement") by mutual agreement. Pursuant to the terms of the Program Purchase Agreement, the Company regained full global rights to research, develop, manufacture and commercialize products resulting from the Servier Agreement, with sole control over all activities.

During the three months ended March 31, 2021 and 2020, the Company recognized revenue under the development and commercial license agreement with Servier of approximately $10.3 million and $2.1 million, respectively. Deferred revenue related to the development and commercial license agreement with Servier amounted to $81.3 million and $82.9 million as of March 31, 2021 and December 31, 2020, respectively, of which $29.4 million and $28.9 million, respectively is included in current liabilities.

Development and License Agreement with Eli Lilly

On November 19, 2020, the Company, entered into a development and license agreement (the "Development and License Agreement") with Eli Lilly and Company ("Lilly") to collaborate to discover and develop *in vivo* gene editing products incorporating the Company's ARCUS nucleases. Lilly has initially nominated Duchenne muscular dystrophy and two other gene targets for other genetic disorders, and has the right to nominate up to three additional gene targets for genetic disorders. Additionally, under the terms of the Development and License Agreement, Lilly has the option to replace up to two gene targets upon Lilly's election and payment of a replacement target fee. Under the terms of the Development and License Agreement, Lilly will receive an exclusive license to research, develop, manufacture and commercialize the resulting licensed products to diagnose, prevent and treat any and all diseases by *in vivo* gene editing directed against the applicable gene target. The Development and License Agreement provides that the Company will be responsible for conducting certain pre-clinical research and investigational new drug application ("IND") enabling activities with respect to the gene targets nominated by Lilly to be subject to the collaboration, including manufacture of initial clinical trial material for the first licensed product. Lilly will be responsible for, and must use commercially reasonable efforts with respect to, conducting clinical development and commercialization activities for licensed products resulting from the collaboration, and may engage the Company for additional clinical and/or initial commercial manufacture of licensed products.

Upon closing of the Development and License Agreement on January 6, 2021, the Company received an upfront cash payment of $100.0 million. The Company will also be eligible to receive milestone payments of up to an aggregate of $420.0 million per licensed product as well as nomination fees for additional targets and certain research funding. If licensed products resulting from the collaboration are approved and sold, the Company will also be entitled to receive tiered royalties ranging from the mid-single digit percentages to the low-teens percentages on world-wide net sales of the licensed products, subject to customary potential reductions. Lilly's obligation to pay royalties to the Company expires on a country-by-country and licensed product-by-licensed product basis, upon the latest to occur of certain events related to expiration of patents, regulatory exclusivity or a period of ten years following first commercial sale of the licensed product. Simultaneously with the entry into the Development and License Agreement, the Company and Lilly entered into a Share Purchase Agreement (the "Share Purchase Agreement"), pursuant to which Lilly purchased 3,762,190 shares of the Company's common stock for a purchase price of $35.0 million. Management concluded that the Lilly Share Purchase Agreement is to be combined with the Development and License Agreement (together, the "Combined Agreements") for accounting purposes. Of the total $135.0 million upfront compensation, the Company applied equity accounting guidance to measure the $27.7 million recorded in equity upon the issuance of the shares, and $107.3 million was identified as the transaction price allocated to the revenue arrangement.

The Company assessed this arrangement in accordance with ASC 606 and concluded that the promises in the agreement represent transactions with a customer. The Company has determined that the promises associated with the research and development activities for each of the targets are not distinct because they are all based on the ARCUS proprietary genome editing platform. The Company has concluded that the agreement with Lilly contains the following promises: (i) license of intellectual property; (ii) performance of R&D services, (iii) the manufacture of pre-clinical supply, (iv) Joint Steering Committee ("JSC") Participation, and (v) regulatory responsibilities. The Company determined that the license of intellectual property, R&D services, manufacture of pre-clinical development material, and regulatory responsibilities were not distinct from each other, as the license, R&D services, pre-clinical supply, and regulatory responsibilities are highly interdependent upon one another. The JSC participation was determined to be an immaterial promise as the time commitment and related cost associated with performance of JSC participation is expected to be inconsequential to the total consideration in the contract. As such, the Company determined that these promises should be combined into a single performance obligation.

The Company recognizes revenue from the $100.0 million upfront cash payment, $7.3 million allocated to the transaction price from the Stock Purchase Agreement, and variable consideration on an input method in the form of research effort relative to expected research effort at the completion of the performance obligation, which is based on the actual time of R&D activities performed relative to expected time to be incurred in the future to satisfy the performance obligation. Management evaluates and adjusts the total expected research effort for the performance obligation on a quarterly basis based upon actual research accomplishments and the probability of continuing research efforts in the future. The transfer of control occurs over this time period and, in management's judgment, is the best measure of progress towards satisfying the performance obligation.

During the three months ended March 31, 2021 the Company recognized revenue under the agreement with Lilly of approximately $5.4 million. The Company recognized no revenue under the agreement with Lilly in 2020. Deferred revenue related to the agreement with Lilly amounted to $102.4 million as of March 31, 2021, of which $23.0 million was included in current liabilities as of March 31, 2021. No deferred revenue related to the Development and License Agreement with Lilly was recorded as of December 31, 2020.

Collaboration and License Agreement with Gilead

On July 6, 2020 (the "Termination Notice Date"), Gilead Sciences ("Gilead") notified the Company of its termination of the Collaboration and License Agreement between Gilead and the Company, dated September 10, 2018, as subsequently amended by Amendment No. 1 to the Collaboration and License Agreement, dated March 10, 2020 (as amended, the "Gilead Agreement"). Pursuant to the termination notice, the Gilead Agreement terminated on September 4, 2020, upon which the Company regained full rights and all data it generated for the *in vivo* chronic hepatitis B virus ("HBV") program developed under the Gilead Agreement. The Company is exploring partnership or alternative opportunities to enable the continued development of ARCUS-based HBV therapies, the progression toward the submission of an IND for this product candidate and the reassessment of the timing of such IND submission.

Revenue associated with the combined performance obligation was recognized on a straight-line basis as the R&D services were provided through the Termination Notice Date. During the three months ended March 31, 2021 and 2020, the Company recognized no revenue and approximately $3.3 million of revenue under the Gilead Agreement, respectively. The Company did not have deferred revenue related to the Gilead Agreement as of March 31, 2021 or December 31, 2020. No development or sales-based milestone payments were received under the Gilead Agreement.

NOTE 9: SEGMENT REPORTING

The Company has developed a genome editing platform and performed related research for human therapeutic and agricultural applications. The Company's Chief Operating Decision Maker ("CODM") evaluates the Company's financial performance based on two reportable segments: Therapeutics and Food. The Therapeutics segment is focused on the development of products in the field of immuno-oncology and of novel products outside immuno-oncology to treat human diseases. The Food segment is focused on applying ARCUS to develop food and nutrition products through collaboration agreements with consumer-facing companies. The CODM reviews segment performance and allocates resources based upon segment revenue and segment operating loss of the Therapeutics and Food reportable segments.

Segment operating loss is derived by deducting operational cash expenditures, net, from GAAP revenue. Operational cash expenditures are cash disbursements made that are directly attributable to the reportable segment (including directly attributable research and development and property, equipment, and software expenditures). The reportable segment operational cash expenditures include cash disbursements for compensation, laboratory supplies, purchases of property, equipment and software and procuring services from CROs, CMOs and research organizations.

Certain cost items are not allocated to the Company's reportable segments. These cost items primarily consist of compensation and general operational expenses associated with the Company's executive, business development, finance, operations, human resources and legal functions. The Company does not allocate non-cash income statement amounts to its reportable segments, such as share based compensation, depreciation and amortization, intangible asset impairment charges, non-cash interest expense and losses on the disposal of assets. When reconciling segment operating loss to consolidated loss from operations, the Company makes an adjustment to convert the cash expenditures to the accrual basis to reflect GAAP.

All segment revenue is earned in the United States and there are no intersegment revenues. Additionally, the Company reports assets on a consolidated basis and does not allocate assets to its reportable segments for purposes of assessing segment performance or allocating resources.

Presented below is the financial information with respect to the Company's reportable segments:

	Three Months Ended March 31,	
(in thousands)	**2021**	**2020**
Revenue:		
Therapeutics	$ 15,679	$ 5,473
Food	670	1,525
Total segment revenue	16,349	6,998
Segment operational cash expenditures:		
Therapeutics	$ 22,863	$ 19,257
Food	2,292	2,818
Total segment operational cash expenditures	25,155	22,075
Segment operating loss:		
Therapeutics	$ (7,184)	$ (13,784)
Food	(1,622)	(1,293)
Total segment operating loss	(8,806)	(15,077)
Adjustments to reconcile segment operating loss to consolidated loss from operations:		
Corporate general and administrative cash expenditures	$ (7,944)	$ (5,903)
Interest income received	(53)	(660)
Depreciation and amortization	(2,176)	(2,155)
Amortization of right-of-use asset	(290)	(235)
Share-based compensation	(3,632)	(3,105)
Loss on disposal of assets	23	-
Adjustments to reconcile cash expenditures to GAAP expenses	4,136	(361)
Total consolidated loss from operations	$ (18,742)	$ (27,496)

NOTE 10: SUBSEQUENT EVENTS

On April 9, 2021, the Company entered into a Program Purchase Agreement with Servier (the "Program Purchase Agreement"), pursuant to which the Company reacquired all of its global development and commercialization rights previously granted to Servier pursuant to the Servier Agreement, and terminated the Servier Agreement by mutual agreement pursuant to the terms described herein.

The Program Purchase Agreement terminates the Servier Agreement, pursuant to which the Company has developed certain allogeneic CAR T candidates, including PBCAR0191 and the stealth cell PBCAR19B, each targeting CD19, as well as four additional product targets. Pursuant to the termination and reacquisition, the Company has regained full global rights to research, develop, manufacture and commercialize products resulting from such programs, with sole control over all activities. With respect to products directed to CD19, Servier has certain rights of negotiation, which may be exercised during a specified time period if the Company elects to initiate a process or entertain third party offers for partnering such products.

The Program Purchase Agreement requires the Company to pay an upfront payment of $20.0 million in a combination of cash ($1.25 million) and waiver of earned, but as-yet unpaid milestones totaling $18.75 million that would have been otherwise payable to the Company. The Program Purchase Agreement also requires the Company to make certain payments to Servier based on the achievement of regulatory and commercial milestones for each product, and a low- to mid-single-digit percentage royalty (subject to certain reductions) based on net sales of approved products, if any, resulting from any continued development and commercialization of the programs by the Company, for a period not to exceed ten years after first commercial sale of the applicable product in the United States or certain countries in Europe. If the Company enters into specified product partnering transactions, the Program Purchase Agreement requires the Company to pay to Servier a portion of certain consideration received pursuant to such product partnering transactions in lieu of the foregoing milestones (with the exception of a one-time clinical phase development milestone) and royalties.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our condensed consolidated financial statements and the related notes to those statements included elsewhere in this Quarterly Report on Form 10-Q. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many important factors, including those set forth in Part II. Item 1A. "Risk Factors" of this Quarterly Report on Form 10-Q, our actual results could differ materially from the results described in, or implied by, these forward-looking statements. As used in this Quarterly Report on Form 10-Q, unless the context otherwise requires, references to "we," "us," "our," "the Company" and "Precision" refer to Precision BioSciences, Inc. and its subsidiaries on a consolidated basis.

Overview

We are a life sciences company dedicated to improving life through the application of our pioneering, proprietary ARCUS genome editing platform. We leverage ARCUS in the development of our product candidates, which are designed to treat human diseases and create healthy and sustainable food and agricultural solutions. We are actively developing product candidates in three innovative areas: allogeneic CAR T cell immunotherapy, *in vivo* gene correction, and food. We are currently conducting a Phase 1/2a clinical trial of PBCAR0191 in adult patients with relapsed or refractory ("R/R") non-Hodgkin lymphoma ("NHL"), or R/R B-cell precursor acute lymphoblastic leukemia ("B-ALL"). PBCAR0191 is our first gene-edited allogeneic chimeric antigen receptor ("CAR") T cell therapy candidate targeting CD19. We have received orphan drug designation for PBCAR0191 from the U.S. Food and Drug Administration, ("FDA") for the treatment of acute lymphoblastic leukemia ("ALL"). In August 2020, the FDA granted Fast Track Designation for PBCAR0191 for the treatment of B-ALL. The NHL cohort will include patients with mantle cell lymphoma ("MCL"), an aggressive subtype of NHL, for which we have received orphan drug designation from the FDA. Made from donor-derived T cells modified using our ARCUS genome editing technology, PBCAR0191 recognizes the well characterized tumor cell surface protein CD19, an important and validated target in several B-cell cancers, and is designed to avoid graft-versus-host disease ("GvHD"), a significant complication associated with donor-derived, cell-based therapies. We believe that this trial, which is designed to assess the safety and tolerability of PBCAR0191 at increasing dose levels, as well as to evaluate anti-tumor activity, is the first U.S.-based clinical trial to evaluate an allogeneic CAR T therapy for R/R NHL. Furthermore, we believe that our proprietary, one-step engineering process for producing allogeneic CAR T cells with a potentially optimized cell phenotype, at large scale in a cost-effective manner, will enable us to overcome the fundamental clinical and manufacturing challenges that have limited the CAR T field to date.

In April 2020, we commenced patient dosing in a Phase 1/2a clinical trial with our second allogeneic CAR T cell therapy product candidate, PBCAR20A. PBCAR20A is wholly owned by us and targets the validated tumor cell surface target CD20. It is being investigated in R/R NHL, including those with R/R chronic lymphocytic leukemia ("CLL"), or R/R small lymphocytic lymphoma ("SLL"). A subset of the NHL patients will have the diagnosis of MCL and we have received orphan drug designation for PBCAR20A from the FDA for the treatment of this disease. In February 2021, the study began enrolling patients into dose level 3, a fixed dose of 480 x 10^6 cells with a max dose of 6.0 x 10^6 cells/kg. We expect to provide an interim update for the PBCAR20A study in 2021.

In June 2020, we commenced patient dosing in a Phase 1/2a clinical trial with our third allogenic CAR T cell therapy product candidate, PBCAR269A. PBCAR269A is wholly owned by us and is designed to target B-cell maturation antigen ("BCMA") for the treatment of R/R multiple myeloma and we have received orphan drug designation and Fast Track Designation from the FDA for this indication. The starting dose of PBCAR269A was 6 x 10^5 cells/kg. In February 2021, the study began enrolling patients into its highest dose cohort, dose level 3, 6.0 x 10^6 cells/kg. We expect to provide an interim update for the PBCAR269A study in 2021. We also expect to initiate the combination arm of our ongoing Phase 1/2a clinical study with PBCAR269A and nirogacestat, SpringWorks Therapeutics' investigational gamma secretase inhibitor ("GSI"), in the first half of 2021. In April 2021, we introduced PBCAR269B, a next-generation, BCMA-targeted candidate incorporating stealth cell technology, for the treatment of R/R multiple myeloma. We are conducting IND-enabling studies for PBCAR269B and expect to submit an IND in early 2022.

In November 2020, we announced a research collaboration and exclusive license agreement with Lilly to utilize ARCUS for the research and development of potential *in vivo* therapies for genetic disorders, with an initial focus on Duchenne muscular dystrophy ("DMD") and two other undisclosed gene targets. Under the agreement, Lilly has the right to nominate up to three additional gene targets for genetic disorders over the first four years of the Development and License Agreement, which may be extended to six years upon Lilly's election and payment of an extension fee. In January 2021, we entered into the Development and License Agreement and completed the transactions under the Stock Purchase Agreement. In connection with the closing of the transactions, we received an upfront cash payment of $100.0 million under the Development and License agreement and $35.0 million in exchange for 3,762,190 shares of our common stock under the Stock Purchase Agreement.

In December 2020, we announced interim clinical results from our Phase 1/2a study of PBCAR0191 as a treatment of R/R NHL and R/R B-ALL. As of the November 16, 2020 cutoff, 27 patients including 16 patients with aggressive NHL and 11 patients with aggressive B-ALL were enrolled and evaluated. In this dose escalation and dose expansion study, PBCAR0191 had an acceptable safety profile with no cases of graft versus host disease, no cases of Grade ≥ 3 cytokine release syndrome, and no cases of Grade ≥ 3 neurotoxicity. PBCAR0191 demonstrated longest durability of response to 11 months in B-ALL. PBCAR0191 with enhanced lymphodepletion ("eLD") resulted in objective response rate of 83% (5/6) in NHL and B-ALL as compared to 33% (3/9) in NHL with standard lymphodepletion. Since the December 2020 interim data update, additional patients have been dosed with PBCAR0191 following eLD. We will continue to monitor the results for durability from this eLD regimen and expect to report updated interim results in June at ASCO 2021.

In January 2021, the FDA accepted our IND for PBCAR19B, our next-generation, stealth cell, CD19 allogenic CAR T candidate for patients with CD19-positive malignancies such as those with R/R NHL. The study is expected to begin by the end of May 2021. PBCAR19B will be administered at flat dose levels, beginning at 2.7×10^8 cells, with the ability to dose up to 8.1×10^8 cells per patient, following standard lymphodepletion. The primary objective of the study is to identify the maximum tolerated dose and any dose-limiting toxicities. Additionally, in January 2021, we announced we received a Notice of Allowance from the U.S. Patent and Trademark Office for a patent application covering PBCAR19B. The allowed composition claims of this patent application encompass genetically-modified human T cells comprising the PBCAR19B construct, which is inserted within the T cell receptor alpha constant locus. Once issued, patents arising from this patent family will have standard expiration dates in April 2040. In preclinical studies, PBCAR19B has shown to delay both T cell and natural killer cell mediated allogeneic rejection in vitro and may improve the persistence of allogeneic CAR T cells.

Also in January 2021, we disclosed our intention to spinout our wholly owned subsidiary, Elo Life Systems, Inc. ("Elo"). We are continuing to explore our strategic options, and expect that we will complete any such spinout, sale or other treatment of Elo in 2021.

In April 2021, we entered into the Program Purchase Agreement with Servier to reacquire all global development and commercialization rights for all CAR T partnered programs covered under the Servier Agreement. This includes our two clinical stage CD19-targeting allogeneic CAR T candidates, PBCAR0191 and PBCAR19B stealth cell, as well as four additional product targets. Under the terms of the Program Purchase Agreement, we paid $1.25 million in cash to Servier and agreed to waive earned, but as-yet unpaid milestones totaling $18.75 million that would have otherwise been payable to us. Servier is also eligible to receive milestones and low- to mid-single-digit royalties subject to product development achievement.

We expect to advance a program targeting the rare genetic disease primary hyperoxaluria type 1 ("PH1") as our lead wholly owned *in vivo* gene correction program. PH1 affects approximately 1-3 people per million in the United States and is caused by loss of function mutations in the AGXT gene, leading to the accumulation of calcium oxalate crystals in the kidneys. Patients suffer from painful kidney stones which may ultimately lead to renal failure. Using ARCUS, we are developing a potential therapeutic approach to PH1 that involves knocking out a gene called HAO1 which acts upstream of AGXT. Suppressing HAO1 has prevented the formation of calcium oxalate in preclinical models. We therefore believe that a one-time administration of an ARCUS nuclease targeting HAO1 may be a viable strategy for a durable treatment of PH1 patients. Pre-clinical research has continued to progress, and we expect to provide an update on the PH1 program in mid-2021.

Since our formation in 2006, we have devoted substantially all of our resources to developing ARCUS, conducting research and development activities, recruiting skilled personnel, developing manufacturing processes, establishing our intellectual property portfolio and providing general and administrative support for these operations. We have financed our operations primarily with proceeds from upfront payments from collaboration and licensing agreements, our initial public offering ("IPO"), and private placements of convertible preferred stock and convertible debt.

Since our inception, we have incurred significant operating losses and have not generated any revenue from the sale of products. Our ability to generate any product revenue or product revenue sufficient to achieve profitability will depend on the successful development and eventual commercialization of one or more of our product candidates or the product candidates of our collaborators for which we may receive milestone payments or royalties. Our net losses were $18.7 million and $26.8 million for the three months ended March 31, 2021 and 2020, respectively. As of March 31, 2021, we had an accumulated deficit of $304.8 million.

We expect our operating expenses to increase substantially in connection with the expansion of our product development programs and capabilities. We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for one of our product candidates or the product candidates of our collaborators for which we may receive milestone payments or royalties. If we obtain regulatory approval for any of our product candidates, we expect to incur significant expenses related to developing our commercialization capability to support product sales, marketing and distribution. In addition, we expect to continue to incur additional costs associated with operating as a public company.

As a result of these anticipated expenditures, we will need additional financing to support our continuing operations. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our cash needs through a combination of

public equity, debt financings or other sources, which may include current and new collaborations with third parties. Adequate additional financing may not be available to us on acceptable terms, or at all. Our inability to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We cannot assure you that we will ever generate significant revenue to achieve profitability.

Because of the numerous risks and uncertainties associated with the development of therapeutic and agricultural products, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate revenue from product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be required to raise additional capital on terms that are unfavorable to us or we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

We currently conduct our operations through two reportable segments: Therapeutics and Food. Our Therapeutics segment is focused on allogeneic CAR T immunotherapy and *in vivo* gene correction. Our Food segment focuses on applying ARCUS to develop food and nutrition products through collaboration agreements with consumer-facing companies.

Impact of COVID-19 Pandemic

We are closely monitoring how the ongoing COVID-19 pandemic continues to affect our employees, business, preclinical studies and clinical trials. The Company has taken steps in line with guidance from the U.S. CDC and the State of North Carolina to protect the health and safety of its employees and the community. We have implemented measures to mitigate exposure risks and support operations. We initiated a health and safety program addressing mandatory use of face masks, social distancing, sanitary handwashing practices, use of personal protective equipment stations, stringent cleaning and sanitization of all facilities and measures to reduce total occupancy in facilities. We have also implemented temperature and symptom screening procedures at each location, and we have continuously communicated to all our Precisioneers that if they are not comfortable coming to work, regardless of role, then they do not have to do so.

We are working closely with our clinical sites, physician partners and the patient community to monitor and manage the impact of the evolving COVID-19 pandemic. We remain committed to our clinical programs and development plans, however, disruptions, competing resource demands and safety concerns caused by the COVID-19 pandemic have caused, and are likely to continue to cause delays in our clinical trial site activation and impact our ability to enroll patients. We may also experience other difficulties, disruptions or delays in conducting preclinical studies or initiating, enrolling, conducting or completing our planned and ongoing clinical trials, and we may incur other unforeseen costs as a result. We expect that the COVID-19 pandemic may continue to impact our business, including our preclinical studies and clinical trials. At this time, there is still significant uncertainty relating to the trajectory of the COVID-19 pandemic and impact of related responses. The impact of COVID-19 on our preclinical studies and any further impact to our clinical trials will largely depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions, the ultimate impact of COVID-19 on financial markets and the global economy, and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. The Coronavirus, Aid, Relief and Economic Security Act ("CARES Act") was signed into law on March 27, 2020, which provides for, among other things, the deferral of the deposit and payment of certain taxes. Pursuant to the CARES Act, we continue to elect to defer payment of the employer's share of social security taxes since May 1, 2020. See *"Risk Factors— The outbreak of the ongoing novel coronavirus disease, COVID-19 has impacted our business, or and any other pandemic, epidemic or outbreak of an infectious disease may materially and adversely impact our business, including our preclinical studies and clinical trials."* In Part II, Item 1A. of this Quarterly Report on Form 10-Q.

Therapeutics Segment Collaborations

Eli Lilly and Company

In November 2020, we entered into a research collaboration and exclusive license agreement with Lilly to utilize ARCUS for the research and development of potential *in vivo* therapies for genetic disorders. Lilly has initially nominated DMD and two gene targets for other genetic disorders, and has the right to nominate up to three additional gene targets for genetic disorders over the first four years of the Development and License Agreement (the "Nomination Period"). Lilly may extend the Nomination Period for an additional two years from the date on which such initial Nomination Period ends, upon Lilly's election and payment of an extension fee. Under the terms of the Development and License Agreement, Lilly will receive an exclusive license to research, develop, manufacture and commercialize the resulting licensed products to diagnose, prevent and treat any and all diseases by *in vivo* gene editing directed against the applicable gene target. The Development and License Agreement provides that we will be responsible for conducting certain pre-clinical research and IND-enabling activities with respect to the gene targets nominated by Lilly to be subject to the collaboration, including manufacture of initial clinical trial material for the first licensed product. Lilly will be responsible for, and must use commercially reasonable efforts with respect to, conducting clinical development and commercialization activities for licensed products resulting from the collaboration, and may engage us for additional clinical and/or initial commercial manufacture of licensed products.

In January 2021, we and Lilly closed the Development and License Agreement. In connection with the closing, we received an upfront cash payment of $100.0 million in cash, as well as $35.0 million from Lilly's purchase of 3,762,190 newly issued shares of our common stock pursuant to a stock purchase agreement as described below. We will also be eligible to receive milestone payments of up to an aggregate of $420.0 million per licensed product as well as nomination fees for additional targets and certain research funding. If licensed products resulting from the collaboration are approved and sold, we will also be entitled to receive tiered royalties ranging from the mid-single digit percentages to the low-teens percentages on world-wide net sales of the licensed products, subject to customary potential reductions. Lilly's obligation to pay royalties to us expires on a country-by-country and licensed product-by-licensed product basis, upon the latest to occur of certain events related to expiration of patents, regulatory exclusivity or a period of ten years following first commercial sale of the licensed product.

We have the right to elect to co-fund the clinical development of one licensed product, which may be selected from among the third or any subsequent licensed products to reach IND filing. If we elect to co-fund such licensed product, we would reimburse Lilly for a portion of the clinical development expenses for such product and, in exchange, each royalty tier with respect to net sales of such licensed product would be increased by a low single digit percentage. During the term of the Development and License Agreement, we may not (and may not license or collaborate with any third party to) research, develop, or commercialize any *in vivo* gene editing product directed against any gene targets that have been nominated and are subject to the Development and License Agreement.

Unless earlier terminated, the Development and License Agreement will remain in effect on a licensed product-by-licensed product and country-by-country basis until the expiration of a defined royalty term for each licensed product and country. Lilly has the right to terminate the Development and License Agreement for convenience by providing advance notice to us. Either party may terminate the Development and License Agreement (i) for material breach by the other party and a failure to cure such breach within the time period specified in the agreement or (ii) due to a challenge to its patents brought by the other party.

During the three months ended March 31, 2021 we recognized revenue under the agreement with Lilly of approximately $5.4 million. We did not recognize any revenue under the agreement with Lilly in 2020. Deferred revenue related to the agreement with Lilly amounted to $102.4 million as of March 31, 2021, of which $23.0 million was included in current liabilities as of March 31, 2021. No deferred revenue related to the Lilly Agreement was recorded as of December 31, 2020.

Servier

In February 2016, we entered into the Servier Agreement, pursuant to which we agreed to develop allogeneic CAR T cell therapies for five unique antigen targets. One target was selected at the agreement's inception. Two additional hematological cancer targets beyond CD19 and two new solid tumor targets were selected in 2020. With the addition of these new targets, we received development milestone payments in 2020. Upon selection of an antigen target under the agreement, we agreed to perform early-stage research and development on individual T cell modifications for the selected target, develop the resulting therapeutic product candidates through Phase 1 clinical trials and prepare initial clinical trial material of such product candidates for use in Phase 2 clinical trials.

In April 2021, we entered into the Program Purchase Agreement with Servier to reacquire all global development and commercialization rights for all CAR T partnered programs covered under the Servier Agreement. This includes our two clinical stage CD19-targeting allogeneic CAR T candidates, PBCAR0191 and PBCAR19B stealth cell, as well as four additional product targets.

Under the terms of the Program Purchase Agreement, we paid $1.25 million in cash to Servier and agreed to waive earned, but as-yet unpaid milestones totaling $18.75 million that would have otherwise been payable to us. The Program Purchase Agreement also requires us to make certain payments to Servier based on the achievement of regulatory and commercial milestones for each product, and a low- to mid-single-digit percentage royalty (subject to certain reductions) based on net sales of approved products, if any, resulting from any continued development and commercialization of the programs, for a period not to exceed ten years after first commercial sale of the applicable product in the United States or certain countries in Europe. If we enter into specified product partnering transactions, the Program Purchase Agreement requires us to pay to Servier a portion of certain consideration received pursuant to such product partnering transactions in lieu of the foregoing milestones (with the exception of a one-time clinical phase development milestone) and royalties.

Under the Servier Agreement, we recognized $10.3 million and $2.1 million in revenue during the three months ended March 31, 2021 and 2020, respectively. The amount recorded as deferred revenue was $81.3 million and $82.9 million as of March 31, 2021 and December 31, 2020, respectively.

SpringWorks Therapeutics

In September 2020, we entered into a Clinical Trial Collaboration Agreement with SpringWorks. Pursuant to the agreement, PBCAR269A will be evaluated in combination with nirogacestat, SpringWorks' investigational GSI, in patients with R/R multiple myeloma. Under the terms of the agreement, we will bear all costs with the conduct of the clinical trial including providing PBCAR269A for use in the trial, and SpringWorks is responsible for providing nirogacestat at its sole cost and expense. We expect to initiate the combination arm of our ongoing Phase 1/2a clinical study with PBCAR269A and nirogacestat in the first half of 2021.

Gilead

On July 6, 2020, Gilead Sciences ("Gilead") notified us of its termination of the collaboration and license agreement dated September 10, 2018, subsequently amended by Amendment No. 1 dated March 10, 2020 or (the "Gilead Agreement"), to develop genome editing tools using ARCUS to target viral DNA associated with the hepatitis B virus. Pursuant to the termination notice, the Gilead Agreement terminated on September 4, 2020. Upon termination, we regained full rights and all data we generated for the *in vivo* chronic hepatitis B program developed under the Gilead Agreement.

We recognized no revenue and $3.3 million in revenue under the Gilead Agreement during the three months ended March 31, 2021 and 2020, respectively. We did not receive any milestone payments under the Gilead Agreement.

Trustees of the University of Pennsylvania

In January 2018, we entered into a research, collaboration and license agreement with the Trustees of the University of Pennsylvania ("Penn") to collaborate on the preclinical development for gene editing products involving the delivery of an ARCUS nuclease. On April 29, 2020, both parties agreed to coordinate a wind-down of all activities in their entirety under the agreement, effective as of June 30, 2020, however, in August 2020 and subsequently in January 2021, both parties agreed to extend certain portions of the agreement until 2022. We will not be required to make termination payments to Penn.

Duke University

In April 2006, we entered into the Duke License, pursuant to which Duke University ("Duke") granted us an exclusive (subject to certain non-commercial rights reserved by Duke), sublicensable, worldwide license under certain patents related to certain meganucleases and methods of making such meganucleases owned by Duke to develop, manufacture, use and commercialize products and processes that are covered by such patents, in all fields and in all applications. For additional discussion of the Duke License, see "Item 1. Business—License and Collaboration Agreements" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020.

Food Segment Collaborations

Dole Food Company

Through our wholly owned subsidiary, Elo, in June 2020, we entered into a Research, Development, and Commercialization Agreement with Dole with the aim to co-develop banana varieties resistant to Foc TR4, utilizing proprietary computational biology workflows and the ARCUS genome editing platform. The disease caused by Foc TR4, commonly known as Fusarium wilt, threatens the continued cultivation of the world's most popular variety of banana called Cavendish, which is of considerable economic significance as this variety is used to produce export bananas for key markets around the globe and Dole is one of the largest producers in the industry. Fungicides, or other traditional means of disease control have failed as the pandemic continues to spread across vital banana growing economies. Development of Foc TR4 varieties is critically important to save the banana industry, to protect the livelihoods of millions of banana growers and continue to provide consumers an affordable and nutritious fruit. Under the terms of the collaboration, Dole will fully fund research and development efforts executed by Elo, and Elo is eligible to receive royalties on any commercialized plant product.

Components of Our Results of Operations

Revenue

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from product sales in the foreseeable future. We record revenue from collaboration agreements, including amounts related to upfront payments, milestone payments, annual fees for licenses of our intellectual property and research and development funding.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our discovery efforts and the development of our product candidates. These include the following:

- salaries, benefits and other related costs, including share-based compensation expense, for personnel engaged in research and development functions;
- expenses incurred under agreements with third parties, including contract research organizations ("CROs") and other third parties that conduct preclinical research and development activities and clinical trials on our behalf;
- costs of developing and scaling our manufacturing process and manufacturing drug products for use in our preclinical studies and ongoing and future clinical trials, including the costs of contract manufacturing organizations ("CMOs") and our MCAT facility that will manufacture our clinical trial material for use in our preclinical studies and ongoing and potential future clinical trials;
- costs of outside consultants, including their fees and related travel expenses;
- costs of laboratory supplies and acquiring, developing and manufacturing preclinical study and clinical trial materials;
- license payments made for intellectual property used in research and development activities; and
- facility-related expenses, which include direct depreciation costs and expenses for rent and maintenance of facilities and other operating costs if specifically identifiable to research activities.

We expense research and development costs as incurred. We track external research and development costs, including the costs of laboratory supplies and services, outsourced research and development, clinical trials, contract manufacturing, laboratory equipment and maintenance and certain other development costs, by product candidate if and when the program IND is accepted by the FDA. Internal and external costs associated with infrastructure resources, other research and development costs, facility related costs and depreciation and amortization that are not identifiable to a specific product candidate are included in the platform development, early-stage research and unallocated expenses category.

Research and development activities are central to our business model. We expect that our research and development expenses will continue to increase substantially for the foreseeable future and will comprise a larger percentage of our total expenses as we continue our Phase 1/2a clinical trials for our CD19, CD20 and BCMA product candidates, commence our Phase 1 clinical trial of CD19B, and continue to discover and develop additional product candidates.

We cannot determine with certainty the duration and costs of ongoing and future clinical trials of our CD19, CD19B, CD20, and BCMA product candidates, or any other product candidate we may develop or if, when or to what extent we will generate revenue from the commercialization and sale of any product candidate for which we obtain marketing approval. We may never succeed in obtaining marketing approval for any product candidate. The duration, costs and timing of clinical trials and development of our CD19, CD19B, CD20, and BCMA product candidates, and any other our product candidate we may develop will depend on a variety of factors, including:

- the scope, rate of progress, expense and results of clinical trials of our CD19, CD19B, CD20, and BCMA product candidates, as well as of any future clinical trials of other product candidates and other research and development activities that we may conduct;
- increased costs of additional clinical sites to address slowed enrollment due to the impact of COVID-19;
- uncertainties in clinical trial design and patient enrollment rates;
- the actual probability of success for our product candidates, including their safety and efficacy, early clinical data, competition, manufacturing capability and commercial viability;
- significant and changing government regulation and regulatory guidance;
- the timing and receipt of any marketing approvals; and

- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in our clinical trials due to slower than expected patient enrollment or other reasons, we would be required to expend significant additional financial resources and time on the completion of clinical development.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including share-based compensation, for personnel in our executive, finance, business development, operations and administrative functions. General and administrative expenses also include legal fees relating to intellectual property and corporate matters; professional fees for accounting, auditing, tax and consulting services; insurance costs; travel expenses; and facility-related expenses, which include direct depreciation costs and expenses for rent and maintenance of facilities and other operating costs that are not specifically attributable to research activities.

We expect that our general and administrative expenses will increase in the future as we continue research activities and development of product candidates.

Interest Income

Interest income consists of interest income earned on our cash and cash equivalents.

Results of Operations

Comparison of the Three Months Ended March 31, 2021 and March 31, 2020

The following table summarizes our results of operations for the three months ended March 31, 2021 and March 31, 2020, together with the changes in those items in dollars:

	Three Months Ended March 31,		
(in thousands)	**2021**	**2020**	**Change**
Revenue	$ 16,349	$ 6,998	$ 9,351
Operating expenses:			
Research and development	25,593	24,879	714
General and administrative	9,498	9,615	(117)
Total operating expenses	35,091	34,494	597
Loss from operations	(18,742)	(27,496)	8,754
Other income, net:			
Interest income	53	660	(607)
Total other income, net	53	660	(607)
Net loss	$ (18,689)	$ (26,836)	$ 8,147

Revenue

Revenue for the three months ended March 31, 2021 was $16.3 million, compared to $7.0 million for the three months ended March 31, 2020. The increase of $9.3 million in revenue during the three months ended March 31, 2021 was primarily the result of a $8.2 million increase in collaboration revenue recognized from Servier, a $5.4 million increase in collaboration revenue recognized from Lilly, partially offset by a decrease of $3.3 million in revenue from Gilead and a $1.0 million decrease in revenue recognized from food segment partners.

Research and Development Expenses

(in thousands)	Three Months Ended March 31, 2021	2020	Change
Direct research and development expenses by product candidate:			
CD19 external development costs	$ 2,216	$ 2,337	$ (121)
CD20 external development costs	789	1,153	(364)
BCMA external development costs	1,056	600	456
CD19B external development costs	1,259	—	1,259
Platform development, early-stage research and unallocated expenses:			
Employee-related costs	10,602	9,104	1,498
Laboratory supplies and services	3,784	3,658	126
Sublicensing revenue payable to Duke	1,111	—	1,111
Outsourced research and development	598	2,752	(2,154)
CMOs and research organizations	284	1,651	(1,367)
Laboratory equipment and maintenance	489	353	136
Facility-related costs	900	802	98
Depreciation and amortization	1,833	1,839	(6)
Licensing fees	546	568	(22)
Other research and development costs	126	62	64
Total research and development expenses	$ 25,593	$ 24,879	$ 714

Research and development expenses for the three months ended March 31, 2021 were $25.6 million, compared to $24.9 million for the three months ended March 31, 2020. The increase of $0.7 million was primarily due to increases of $0.5 million and $1.3 million in direct research and development expenses related to our BCMA and CD19B programs, respectively. The increase in direct research and development expenses for our BCMA program was primarily due to an increase in research organization expenses as we continue to enroll additional patients in the Phase 1/2a clinical trial that commenced in 2020. The increase in direct research and development expenses for our CD19B program was primarily due to increases in lab services expense, CMO expense and research organization expense as we prepare to commence our Phase 1 clinical trial of CD19B in mid-2021. These increases were partially offset by decreases of $0.1 million and $0.4 million related to our CD19 and CD20 programs, respectively, as we completed technology transfer of CD19 and CD20 to our manufacturing facility in 2020, in addition to a decrease of $0.6 million in platform development, early-stage research and unallocated expense.

Platform development, early-stage research and unallocated expenses decreased primarily due to a $2.2 million decrease in outsourced research and development expense and a $1.4 million decrease in CMO and research organization expense. This was partially offset by a $1.5 million increase in employee-related costs associated with increased headcount to support our technology platform development and manufacturing capabilities, a $1.1 million sublicensing revenue payable to Duke, and a $0.4 million increase in various other research and development costs in the three months ended March 31, 2021 compared to the same period in 2020.

General and Administrative Expenses

General and administrative expenses were $9.5 million for the three months ended March 31, 2021 compared to $9.6 million for the three months ended March 31, 2020. The decrease of $0.1 million was primarily due to a $0.4 million decrease in consulting fees, partially offset by a $0.3 million increase in director and officer insurance expense.

Interest Income

Interest income was $0.1 million for the three months ended March 31, 2021 compared to $0.7 million for the three months ended March 31, 2020. The decrease of $0.6 million of interest income was the result of lower interest rates in three months ended March 31, 2021, compared to the same period in 2020.

Segment Results

The following tables summarize segment revenues and segment operating loss (see Note 9 to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for additional information regarding our segments):

	Three Months Ended March 31,	
(in thousands)	**2021**	**2020**
Revenue:		
Therapeutics	$ 15,679	$ 5,473
Food	670	1,525
Total segment revenue	16,349	6,998
Segment operational cash expenditures:		
Therapeutics	$ 22,863	$ 19,257
Food	2,292	2,818
Total segment operational cash expenditures	25,155	22,075
Segment operating loss:		
Therapeutics	$ (7,184)	$ (13,784)
Food	(1,622)	(1,293)
Total segment operating loss	(8,806)	(15,077)

We evaluate the operating performance of each segment based on segment operating loss. Segment operating loss is derived by deducting operational cash expenditures, net, from GAAP revenue. Operational cash expenditures are cash disbursements made that are specifically identifiable to the reportable segment (including specifically identifiable research and development and property, equipment and software expenditures). The reportable segment operational cash expenditures include cash disbursements for compensation, laboratory supplies, purchases of property, equipment and software and procuring services from CROs, CMOs and research organizations. We do not allocate general operational expenses or non-cash income statement amounts to our reportable segments.

Therapeutics Segment

Revenue for the three months ended March 31, 2021 was $15.7 million, compared to $5.5 million for the three months ended March 31, 2020. The increase of $10.2 million was primarily the result of a $8.2 million increase in collaboration revenue recognized from Servier and a $5.4 million increase in revenue recognized from Lilly, partially offset by a $3.3 million decrease in revenue recognized from Gilead.

Segment operational cash expenditures for the three months ended March 31, 2021 were $22.9 million, compared to $19.3 million for the three months ended March 31, 2020. The increase of $3.6 million was primarily due to increases in employee headcount, clinical trial activity across CD19B and BCMA clinical trials and scientific service providers. Segment operating loss decreased by $6.6 million to $7.2 million for the three months ended March 31, 2021 compared to $13.8 million for three months ended March 31, 2020 primarily due to the factors discussed above.

Food Segment

Revenue for the three months ended March 31, 2021 was $0.7 million, compared to $1.5 million for the three months ended March 31, 2020. The decrease of $0.8 million was attributable to a $1.5 million decrease in revenue recognized from an agriculture industry collaboration partner, partially offset by a $0.7 million increase in revenue recognized from Dole.

Segment operational cash expenditures for the three months ended March 31, 2021 were $2.3 million, compared to $2.8 million for the three months ended March 31, 2020. The decrease of $0.5 million was primarily due to a decrease in fixed asset purchases. Segment operating loss increased $0.3 million to $1.6 million for the three months ended March 31, 2021 compared to $1.3 million for the three months ended March 31, 2020 primarily due to the factors discussed above.

Liquidity and Capital Resources

Since our inception, we have incurred significant operating losses. We expect to incur significant expenses and operating losses for the foreseeable future as we advance the preclinical and clinical development of our product candidates. We expect that our research and development and general and administrative costs will continue to increase, including in connection with conducting preclinical studies and clinical trials for our product candidates, contracting with CROs and CMOs, the addition of laboratory equipment to MCAT in support of preclinical studies and clinical trials, expanding our intellectual property portfolio and providing general and

administrative support for our operations. As a result, we will need additional capital to fund our operations, which we may obtain from additional equity or debt financings, collaborations, licensing arrangements or other sources.

There are no assurances that we will be successful in obtaining an adequate level of financing as and when needed to finance our operations on terms acceptable to us or at all, particularly in light of the economic downturn and ongoing uncertainty related to the COVID-19 pandemic. If we are unable to secure adequate additional funding as and when needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more product candidates. In addition, the magnitude and duration of the COVID-19 pandemic and its impact on our liquidity and future funding requirements remains uncertain as of the filing date of this Quarterly Report on Form 10-Q, as the pandemic continues to evolve globally. See "Impact of COVID-19 Pandemic" above and *"Risk Factors— The ongoing novel coronavirus disease, COVID-19 has impacted our business and any other pandemic, epidemic or outbreak of an infectious disease may materially and adversely impact our business, including our preclinical studies and clinical trials"* in Part II, Item 1A. of this Quarterly Report on Form 10-Q for a further discussion of the potential impact of the COVID-19 pandemic on our business.

We do not currently have any approved products and have never generated any revenue from product sales. Through the date of filing this Quarterly Report on Form 10-Q, we have financed our operations primarily with proceeds from our IPO, private placements of our convertible preferred stock, convertible debt and common stock, and upfront payments from collaboration and licensing arrangements. As of March 31, 2021, we had raised approximately $627.5 million of proceeds from third parties through a combination of financings including our IPO, preferred stock and convertible note financings, upfront and milestone payments from customers and funding from other strategic alliances and grants. We also currently have an effective shelf registration statement on Form S-3 (No. 333-238857) filed with the SEC on June 1, 2020 (the "Form S-3") under which we may offer from time to time in one or more offerings any combination of common and preferred stock, debt securities, warrants and units of up to $200.0 million in the aggregate. As of March 31, 2021, we had not sold any securities under our shelf registration statement.

Cash Flows

Our cash and cash equivalents totaled $193.5 million and $154.2 million as of March 31, 2021 and 2020, respectively.

The following table summarizes our sources and uses of cash for the periods presented:

	Three Months Ended March 31,	
(in thousands)	**2021**	**2020**
Net cash provided by (used in) operating activities	$ 68,072	$ (25,910)
Net cash used in investing activities	(1,125)	(1,103)
Net cash provided by financing activities	36,715	314
Increase (decrease) in cash and cash equivalents	$ 103,662	$ (26,699)

Cash Provided by (Used in) Operating Activities

Our primary use of cash is to fund operating expenses, which consist primarily of research and development and general and administrative expenses. Our losses have resulted from expenses incurred in connection with our research and development activities, including our clinical programs, preclinical development activities, and general and administrative costs associated with our operations. Cash provided by (used in) operating activities during the years ended March 31, 2021 and March 31, 2020 resulted from our net loss adjusted for non-cash expenses and changes in working capital.

Cash provided by operating activities during the three months ended March 31, 2021 was $68.1 million, compared to $25.9 million used in operating activities during the three months ended March 31, 2020. The increase in cash flows for operating activities in the three months ended March 31, 2021 was primarily driven by the $100.0 million upfront payment received from Lilly in January 2021, partially offset by increases in employee-related costs associated with increased headcount and increased costs related to our clinical programs with our ongoing clinical trials and preparation for our CD19B clinical trial.

Cash Used in Investing Activities

Cash used in investing activities primarily relates to leasehold additions, equipment and software. Net cash used in investing activities during the three months ended March 31, 2021 was $1.1 million, compared to $1.1 million in the three months ended March 31, 2020.

Cash Provided by Financing Activities

Net cash provided by financing activities during the three months ended March 31, 2021 was $36.7 million, compared to $0.3 million during the three months ended March 31, 2020. The higher cash provided by financing activities during the three months ended March 31, 2021 compared to the year ended March 31, 2020, was primarily due to the $35.0 million in proceeds received under the Stock Purchase Agreement with Lilly in January 2021 and an increase in proceeds received from stock option exercises.

Debt Obligations

In May 2019, we entered into a loan and security agreement with Pacific Western Bank, as subsequently amended pursuant to which we may request advances on a revolving line of credit of up to an aggregate principal of $30.0 million.

The Pacific Western Loan matures on June 23, 2023. All outstanding principal amounts are due on the maturity date. The Company must also maintain an aggregate balance of unrestricted cash at Bank (not including amounts in certain specified accounts) equal to or greater than $10.0 million. The interest rate under the Pacific Western Loan is a variable annual rate equal to the greater of (a) 2.75% above the Prime Rate (as defined in the Pacific Western Loan), or (b) 6.00%.

There have been no borrowings under the Pacific Western Loan as of the date of this Quarterly Report on Form 10-Q. The Company was in compliance with its financial covenants under the Pacific Western Loan as of March 31, 2021.

Funding Requirements

Our operating expenses increased substantially in the three months ended March 31, 2021 and are expected to continue to increase in the future in connection with the continuation of our current clinical trials, planned initiation of additional clinical trials and expected growth in our portfolio.

We believe that our cash and cash equivalents as of March 31, 2021, expected operational receipts and available credit will allow us to continue our operations into 2023. We have based these estimates on assumptions that may prove to be imprecise, and we could utilize our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical and agricultural products, it is difficult to estimate with certainty the amount of our working capital requirements. Our future funding requirements will depend on many factors, including:

- the progress, costs and results of our clinical development for our CD19, CD19B, CD20, and BCMA programs as we progress clinical trials, including CRO costs;
- the progress, costs and results of our additional research and preclinical development programs;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA and other comparable foreign regulatory authorities;
- the costs and timing of internal process development and manufacturing scale-up activities and contract with CMOs associated with our CD19, CD19B, CD20, and BCMA programs and other programs we advance through preclinical and clinical development;
- our ability to establish and maintain strategic collaborations, licensing or other agreements and the financial terms of such agreements;
- the scope, progress, results and costs of any product candidates that we may derive from ARCUS or any other product candidates we may develop alone or with collaborators;
- the extent to which we in-license or acquire rights to other products, product candidates or technologies;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against any intellectual property-related claims; and
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any product candidates for which we or our collaborators obtain marketing approval.

Until such time, if ever, that we can generate product revenue sufficient to achieve profitability, we expect to finance our cash needs through a combination of public or private equity or debt financings, collaboration agreements, other third party funding, strategic alliances, licensing arrangements and marketing and/or distribution arrangements.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, shareholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our shareholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or

restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through other third-party funding, collaboration agreements, strategic alliances, licensing arrangements or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, product development and research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations

There have been no material changes to our contractual obligations from those described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020.

Critical Accounting Policies and Use of Estimates

Our critical accounting policies and estimates are described in "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Use of Estimates" in our Annual Report on Form 10-K. We have reviewed those critical accounting policies and estimates for the three months ended March 31, 2021, and there have been no significant changes in our critical accounting policies and estimates from those disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

Emerging Growth Company Status

We are an "emerging growth company," as defined in the JOBS Act, and we may take advantage of reduced reporting requirements that are otherwise applicable to public companies. Section 107 of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies are required to comply with those standards. We have elected to take advantage of the extended transition period for complying with new or revised accounting standards. As an "emerging growth company," we are also exempted from having to provide an auditor attestation of internal control over financial reporting under Sarbanes-Oxley Act Section 404(b).

We will remain an "emerging growth company" until the earliest of (1) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more, (2) December 31, 2024, (3) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years or (4) the date on which we are deemed to be a large accelerated filer under the rules of the SEC, which means the market value of our common stock held by non-affiliates exceeds $700 million as of the prior June 30th, we have been a public company for at least 12 months and have filed one Annual Report on Form 10-K.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. Our interest-earning assets consist of cash and cash equivalents, which are denominated in U.S. dollars. We had cash and cash equivalents of $193.5 million, or 74% of our total assets, as of March 31, 2021 and $89.8 million, or 60% of our total assets, as of December 31, 2020. Interest income earned on these assets was less than $0.1 million for the three months ended March 31, 2021. Our interest income is sensitive to changes in the general level of interest rates, primarily U.S. interest rates, however, we do not anticipate fluctuations in interest rates to have a significant impact on our financial statements.

We are also exposed to foreign exchange rate risk with respect to our global subsidiaries from foreign currency transactions. We do not anticipate foreign exchange rate risk to have a material impact on our financial statements.

Item 4. Controls and Procedures.

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Interim Chief Financial Officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of as of March 31, 2021.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the three months ended March 31, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time we may be involved in claims and proceedings arising in the course of our business. The outcome of any such claims or proceedings, regardless of the merits, is inherently uncertain. We are not currently party to any material legal proceedings.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. Before investing in our common stock, you should consider carefully the risks described below, together with the other information included or incorporated by reference in this Quarterly Report on Form 10-Q. The occurrence of any of the following risks could materially adversely affect our business, financial condition, results of operations and future growth prospects. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment.

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

We have incurred significant operating losses since our inception and expect to continue to incur losses for the foreseeable future. We have never been profitable, and may never achieve or maintain profitability.

We have never been profitable and do not expect to be profitable in the foreseeable future. Since inception, we have incurred significant operating losses. If our product candidates are not successfully developed and approved, we may never generate any revenue from product sales. Our net losses were $18.7 million for the three months ended March 31, 2021 and $109.0 million for the year ended December 31, 2020. As of March 31, 2021, we had an accumulated deficit of $304.8 million. In addition, we have not commercialized any products and have never generated any revenue from product sales. Substantially all of our losses have resulted from expenses incurred in connection with our research and development activities, including our preclinical development activities, and from general and administrative costs associated with our operations. We have financed our operations primarily through our IPO, preferred stock and convertible note financings, payments from customers and funding from other strategic alliances and grants. The amount of our future net losses will depend, in part, on the amount and growth rate of our expenses and our ability to generate revenues.

All of our current or future product candidates will require substantial additional development time and resources before we may realize revenue from product sales, if at all. We expect to continue to incur significant expenses and operating losses for the foreseeable future. Our expenses have increased and we anticipate will continue to increase substantially if and as we:

- continue our current research and development programs, including conducting laboratory, preclinical and greenhouse studies for product candidates;
- continue to conduct or initiate clinical or field trials for product candidates;
- seek to identify, assess, acquire or develop additional research programs or product candidates;
- maintain, expand and protect our intellectual property portfolio;
- seek marketing approvals for any product candidates that may successfully complete development;
- establish a sales, marketing and distribution infrastructure to commercialize any products that may obtain marketing approval;
- further develop and refine the manufacturing process for our product candidates;
- change or add additional manufacturers or suppliers of biological materials or product candidates;
- further develop our genome editing technology;
- acquire or in-license other technologies;
- seek to attract and retain new and existing personnel;
- expand our facilities; and
- incur increased costs as a result of operating as a public company.

It will be several years, if ever, before we obtain regulatory approval for, and are ready for commercialization of, a therapeutic product candidate. Similarly, no product candidate from our food platform has advanced to field testing, and it will be several years, if ever, before we or our collaborators commercialize any such product candidate. New food and agriculture products using the precise editing

approach generally take approximately three to five years to develop. Even if a therapeutic product candidate receives regulatory approval or a food or agriculture product advances through commercialization, future revenues for such product candidate will depend upon many factors, such as, as applicable, the size of any markets in which such product candidate is approved for sale, the market share captured by such product candidate, including as a result of the market acceptance of such product candidate and the effectiveness of manufacturing, sales, marketing and distribution operations related to such product candidate, the terms of any collaboration or other strategic arrangement we may have with respect to such product candidate and levels of reimbursement from third-party payors. If we are unable to develop and commercialize one or more product candidates either alone or with collaborators, or if revenues from any product candidate that receives marketing approval or is commercialized are insufficient, we may not achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability. If we are unable to achieve and maintain profitability, the value of our common stock will be materially adversely affected.

We will need substantial additional funding, and if we are unable to raise a sufficient amount of capital when needed on acceptable terms, or at all, we may be forced to delay, reduce or eliminate some or all of our research programs, product development activities and commercialization efforts.

The process of identifying product candidates and conducting preclinical or greenhouse studies and clinical or field trials is time consuming, expensive, uncertain and takes years to complete. We expect our expenses to increase in connection with our ongoing activities, particularly as we identify, continue the research and development of, initiate and continue clinical or field trials of, and seek marketing approval for, product candidates. In addition, if any therapeutic product candidate that we develop alone or with collaborators obtains marketing approval, we may incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution efforts. Furthermore, we have incurred, and expect to continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise sufficient capital when needed, we may be forced to delay, reduce or eliminate current or future research programs, product development activities and/or commercialization efforts.

We believe that our cash and cash equivalents as of March 31, 2021, expected operational receipts and available credit will allow the Company to continue its operations into 2023. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our operating plans and other demands on our cash resources may change as a result of many factors, including factors unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other sources, such as strategic collaborations. We do not currently expect future grant revenues to be a material source of revenue.

Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop product candidates. Our future capital requirements will depend on many factors, including:

- the timing, scope, progress, costs, results and analysis of results of research activities, preclinical or greenhouse studies and clinical or field trials for any of our product candidates;
- the costs of future activities, including product manufacturing, sales, marketing and distribution activities for any product candidates that receive regulatory approval;
- the success of our existing collaborative relationships;
- the extent to which we exercise any development or commercialization rights under collaborative relationships;
- our ability to establish and maintain additional collaborative relationships on favorable terms, or at all;
- the extent to which we expand our operations and the timing of such expansion, including with respect to facilities, employees and product development platforms;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property and proprietary rights and defending intellectual property-related claims;
- the extent to which we acquire or in-license other technologies or product candidates;
- the extent to which we acquire or invest in other businesses;
- the costs of continuing to operate as a public company; and
- the amount of revenues, if any, received from commercial sales of any products that we develop alone or with collaborators that receive regulatory approval.

Even if we believe we have sufficient funds for our current or future operating plans, we may continue to seek additional capital if market conditions are favorable or in light of specific strategic considerations. Adequate additional financing may not be available to us on acceptable terms, or at all. If we are unable to obtain sufficient funding on a timely basis or on favorable terms, we may be required to significantly delay, reduce or eliminate one or more of our research or product development programs and/or

commercialization efforts. We may also be unable to expand our operations or otherwise capitalize on business opportunities as desired. Any of these events could materially adversely affect our financial condition and business prospects.

Provisions of our debt instruments may restrict our ability to pursue our business strategies.

Pursuant to the Pacific Western Loan with PWB, we may request advances on a revolving line of credit ("the Revolving Line") of up to an aggregate principal of $30.0 million, the maturity date of the Revolving Line is June 23, 2023. As of March 31, 2021, we had no borrowings under our Revolving Line. Under the loan and security agreement, we granted PWB a security interest in substantially all of our assets, excluding any of the intellectual property now or hereafter owned, acquired or received by us (but including any rights to payment from the sale or licensing of any such intellectual property).

The Pacific Western Loan requires us, and any debt instruments we may enter into in the future may require us, to comply with various covenants that limit our ability to, among other things:

- dispose of assets;
- change our name, location, executive office or executive management, business, fiscal year, or control;
- complete mergers or acquisitions;
- incur indebtedness;
- encumber assets;
- pay dividends or make other distributions to holders of our capital stock;
- make specified investments;
- make capitalized expenditures in excess of $40 million in the aggregate during each fiscal year;
- maintain less than $10.0 million of unrestricted cash at PWB; and
- engage in certain transactions with our affiliates.

These restrictions could inhibit our ability to pursue our business strategies. In addition, we are subject to financial covenants based on minimum cash balances.

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 revenues, we expect to finance our cash needs through a combination of equity and/or debt financings and collaborations, licensing agreements or other strategic arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of such securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. To the extent that we raise additional capital through debt financing, it would result in increased fixed payment obligations and a portion of our operating cash flows, if any, being dedicated to the payment of principal and interest on such indebtedness. In addition, debt financing may involve agreements that include restrictive covenants that impose operating restrictions, such as restrictions on the incurrence of additional debt, the making of certain capital expenditures or the declaration of dividends. To the extent we raise additional capital through arrangements with collaborators or otherwise, we may be required to relinquish some of our technologies, research programs, product development activities, product candidates and/or future revenue streams, license our technologies and/or product candidates on unfavorable terms or otherwise agree to terms unfavorable to us. Furthermore, any capital raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to advance research programs, product development activities or product candidates.

We have a limited operating history, which makes it difficult to evaluate our current business and future prospects and may increase the risk of your investment.

We are a genome editing company with a limited operating history. We formed our company in 2006 and spent the first nine years of our company's history developing and refining our core technology, and only during the past several years have we focused our efforts on advancing the development of product candidates.

Investment in biopharmaceutical and agricultural biotechnology product development is a highly speculative endeavor. It entails substantial upfront capital expenditures, and there is significant risk that any product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, obtain any required regulatory approvals or become commercially viable. Our genome editing platform and the technologies we are using are new and unproven. We have initiated a Phase 1/2a clinical trial in patients with R/R

NHL and R/R B-ALL, a separate Phase 1/2a clinical trial in patients with NHL, CLL and SLL as well as a Phase 1/2a clinical trial in patients with R/R multiple myeloma, but we have not commenced field trials for any of our product candidates from our food platform. We have not yet demonstrated an ability to successfully complete any clinical or field trials, obtain any required marketing approvals, manufacture products, conduct sales, marketing and distribution activities, or arrange for a third party to do any of the foregoing on our behalf. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing products.

Additionally, we encounter risks and difficulties frequently experienced by new and growing companies in rapidly developing and changing industries, including challenges in forecasting accuracy, determining appropriate investments of our limited resources, gaining market acceptance of our technology, managing a complex regulatory landscape and developing new product candidates, which may make it more difficult to evaluate our likelihood of success. Our current operating model may require changes in order for us to adjust to these challenges or scale our operations efficiently. Our limited operating history, particularly in light of the rapidly evolving nature of the biopharmaceutical and agricultural biotechnology industries and the genome editing field, may make it difficult to evaluate our technology and business prospects or to predict our future performance. Additionally, due to the stage of our operations, we expect that our financial condition and operating results may fluctuate significantly from quarter to quarter as a result of many factors as we build our business, and you should not rely upon the results of any particular quarterly or annual period as indications of future operating performance.

We may expend our limited resources on pursuing particular research programs or product candidates that may be less successful or profitable than other programs or product candidates.

Research programs to identify new product candidates and product development platforms require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs, product candidates or product development platforms that ultimately prove to be unsuccessful. Any time, effort and financial resources we expend on identifying and researching new product candidates and product development platforms may divert our attention from, and adversely affect our ability to continue, development and commercialization of existing research programs, product candidates and product development platforms. Clinical trials or field trials, as applicable, of any of our product candidates may never commence despite the expenditure of significant resources in pursuit of their development, and our spending on current and future research and development programs, product candidates and product development platforms may not yield any commercially viable products. As a result of having limited financial and managerial resources, we may forego or delay pursuit of opportunities that later prove to have greater commercial potential. For example, we continue to strategically assess our options in connection with a potential separation of our food segment, Elo, from Precision, which could be as early as during 2021. Our resource allocation decisions may cause us to fail to timely capitalize on viable commercial products or profitable market opportunities. Additionally, 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 strategic arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

We expect to take advantage of a Research and Development Tax Incentive program in Australia, which could be amended or changed.

We may be eligible to receive a financial incentive from the Australian government as part of its Research and Development Tax Incentive program, or R&D Tax Incentive program. The R&D Tax Incentive program is one of the key elements of the Australian government's support for Australia's innovation system and, if eligible, provides the recipient with a 43.5% refundable tax offset for research and development activities in Australia. There have been recent proposals to change the structure of the innovation and research and development funding landscape in Australia, which may impact the research and development tax incentive receivable for the 2021 financial year and beyond. There can be no assurance that we will qualify and be eligible for such incentives or that the Australian government will continue to provide incentives, offset, grants and rebates on similar terms or at all.

Risks Related to the Identification, Development and Commercialization of Our Product Candidates

ARCUS is a novel technology, making it difficult to predict the time, cost and potential success of product candidate development. We have not yet been able to assess the safety and efficacy of most of our product candidates in humans, and have only limited safety and efficacy information in humans to date regarding one of our product candidates.

Our success depends on our ability to develop and commercialize product candidates using our novel genome editing technology. The novel nature of our technology makes it difficult to accurately predict the developmental challenges we may face for product candidates as they proceed through research, preclinical or greenhouse studies and clinical or field trials. There have been a limited number of clinical trials of products created with genome editing technologies, three of which have utilized our technology. Because our therapeutic research programs are all in preclinical or early clinical stages, we have only been able to assess limited safety and efficacy data for one of our product candidates in a human trial. Current or future product candidates may not meet safety and efficacy requirements for continued development or ultimate approval in humans and may cause significant adverse events or toxicities. All of

our product candidates are designed to act at the level of DNA, and because animal DNA differs from human DNA, it will be difficult for us to test our therapeutic product candidates in animal models for either safety or efficacy, and any testing that we conduct may not translate to their effects in humans. Moreover, animal models may not exist for some of the targets, diseases or indications that we intend to pursue. Similarly, we and our collaborators have not yet completed field trials for any agricultural product candidates created with our technology. Our product candidates may not be able to properly implement desired genetic edits with sufficient accuracy to be viable therapeutic or agricultural products, and there may be long-term effects associated with them that we cannot predict at this time. Any problems we experience related to the development of our genome editing technology or any of our or our collaborators' research programs or product candidates may cause significant delays or unanticipated costs, and we may not be able to satisfactorily solve such problems. These factors may prevent us or our collaborators from completing our preclinical or greenhouse studies or any clinical or field trials that we or our collaborators have ongoing or may initiate, or profitably commercializing any product candidates on a timely basis, or at all. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process as we develop and prepare to commercialize product candidates. These factors make it more difficult for us to predict the time, cost and potential success of product candidate development. If our product development activities take longer or cost more than anticipated, or if they ultimately are not successful, it would materially adversely affect our business and results of operations.

The genome editing field is relatively new and evolving rapidly, and other existing or future technologies may provide significant advantages over our ARCUS platform, which could materially harm our business.

To date, we have focused our efforts on optimizing our proprietary genome editing technology and exploring its potential applications. ARCUS is a novel genome editing technology using sequence-specific DNA-cutting enzymes, or nucleases, that is designed to perform modifications in the DNA of living cells and organisms. Other companies have previously undertaken research and development of genome editing technologies using zinc finger nucleases, transcription activator-like effector nucleases ("TALENs") and clustered regularly interspaced short palindromic repeats associated protein-9 nuclease ("CRISPR/Cas9"), although none has obtained marketing approval for a product candidate developed using such technologies. Other genome editing technologies in development or commercially available, or other existing or future technologies, may lead to treatments or products that may be considered better suited for use in human therapeutics or agriculture, which could reduce or eliminate our commercial opportunity.

We are heavily dependent on the successful development and translation of ARCUS, and due to the early stages of our product development operations, we cannot give any assurance that any product candidates will be successfully developed and commercialized.

We are at an early stage of development of the product candidates currently in our programs and are continuing to develop our ARCUS technology. To date, we have invested substantially all of our efforts and financial resources to develop ARCUS and advance our current product development programs, including conducting preclinical studies, early stage clinical trials and other early research and development activities, and providing general and administrative support for these operations. We are also currently using our ARCUS technology to develop our lead *in vivo* gene correction programs targeting DMD and PH1. Our future success is dependent on our ability to successfully develop and, where applicable, obtain regulatory approval for, including marketing approval for, and then successfully commercialize, product candidates, either alone or with collaborators. We have not yet developed and commercialized any product candidates, and we may not be able to do so, alone or with collaborators.

Our research and development programs may not lead to the successful identification, development or commercialization of any products.

The success of our business depends primarily upon our ability to identify, develop and commercialize products using our genome editing technology. With the exception of our CD19, CD20 and BCMA product candidates, all current product candidates and product development programs are still in the discovery, preclinical or greenhouse stages. We may be unsuccessful in advancing those product candidates into clinical development or field trials or in identifying any developing additional product candidates. Our ability to identify and develop product candidates is subject to the numerous risks associated with preclinical and early stage biotechnology development activities, including that:

- the use of ARCUS may be ineffective in identifying additional product candidates;
- we may not be able to assemble sufficient resources to acquire or discover additional product candidates;
- we may not be able to enter into collaborative arrangements to facilitate development of product candidates;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- our product candidates may be covered by third parties' patents or other exclusive rights;

- the regulatory pathway for a product candidate may be too complex, expensive or otherwise difficult to navigate successfully; or

- our product candidates may be shown to not be effective, have harmful side effects or otherwise pose risks not outweighed by such product candidate's benefits or have other characteristics that may make the products impractical to manufacture, unlikely to receive any required marketing approval, unlikely to generate sufficient market demand or otherwise not achieve profitable commercialization.

Our product candidates currently being investigated in clinical trials, or that are expected to be investigated in clinical trials, and other product candidates we may identify may never be approved. Failure to successfully identify and develop new product candidates and obtain regulatory approvals for our products would have a material adverse effect on our business and financial condition and could cause us to cease operations.

If our product candidates do not achieve projected development milestones or commercialization in the announced or expected timeframes, the further development or commercialization of such product candidates may be delayed, and our business will be harmed.

We sometimes estimate, or may in the future estimate, the timing of the accomplishment of various scientific, clinical, manufacturing, regulatory and other product development objectives. These milestones may include our expectations regarding the commencement or completion of scientific studies or clinical or field trials, the submission of regulatory filings, the receipt of marketing approval or the realization of other commercialization objectives. The achievement of many of these milestones may be outside of our control. All of these milestones are based on a variety of assumptions, including assumptions regarding capital resources, constraints and priorities, progress of and results from development activities, the receipt of key regulatory approvals or actions, and other factors, including without limitation, impacts resulting from the COVID-19 pandemic, any of which may cause the timing of achievement of the milestones to vary considerably from our estimates. If we or our collaborators fail to achieve announced milestones in the expected timeframes, the commercialization of the product candidates may be delayed, our credibility may be undermined, our business and results of operations may be harmed, and the trading price of our common stock may decline.

Adverse public perception of genome editing may negatively impact the developmental progress or commercial success of products that we develop alone or with collaborators.

The developmental and commercial success of our current product candidates, or any that we develop alone or with collaborators in the future, will depend in part on public acceptance of the use of genome editing technology for the prevention or treatment of human diseases or for application in food or agricultural products. Adverse public perception of applying genome editing technology for these purposes may negatively impact our ability to raise capital or enter into strategic agreements for the development of product candidates.

The commercial success of any food or agricultural products that we develop alone or with collaborators may be adversely affected by claims that biotechnology plant products are unsafe for consumption or use, pose risks of damage to the environment or create legal, social or ethical dilemmas. Additionally, the public may perceive any potential food or agricultural products created with ARCUS to constitute genetically modified organisms ("GMOs"), even if they do not constitute genetically modified organisms under relevant regulatory requirements, and may be unwilling to consume them because of negative opinions regarding consumption of genetically modified organisms. This may result in expenses, delays or other impediments to development programs in our food platform or the market acceptance and commercialization of any potential food or agricultural products.

Any therapeutic product candidates may involve editing the human genome. The commercial success of any such potential therapeutic products, if successfully developed and approved, may be adversely affected by claims that genome editing is unsafe, unethical or immoral. This may lead to unfavorable public perception and the inability of any therapeutic product candidates to gain the acceptance of the public or the medical community. Unfavorable public perceptions may also adversely impact our or our collaborators' ability to enroll clinical trials for therapeutic product candidates. Moreover, success in commercializing any therapeutic product candidates that receive regulatory approval will depend upon physicians prescribing, and their patients being willing to receive, treatments that involve the use of such product candidates in lieu of, or in addition to, existing treatments with which they are already familiar and for which greater clinical data may be available. Publicity of any adverse events in, or unfavorable results of, preclinical studies or clinical trials for any current or future product candidates, including, without limitation, patient deaths, or with respect to the studies or trials of our competitors or of academic researchers utilizing genome editing technologies, even if not ultimately attributable to our technology or product candidates, could negatively influence public opinion. Negative public perception about the use of genome editing technology in human therapeutics and food or agricultural products, whether related to our technology or a competitor's technology, could result in increased governmental regulation, delays in the development and commercialization of product candidates or decreased demand for the resulting products, any of which may have a negative impact on our business and financial condition.

We face significant competition in industries experiencing rapid technological change, and there is a possibility that our competitors may achieve regulatory approval before us or develop product candidates or treatments that are safer or more effective than ours, which may harm our financial condition and our ability to successfully market or commercialize any of our product candidates.

The development and commercialization of new drug products is highly competitive, and the genome editing field is characterized by rapidly changing technologies, significant competition and a strong emphasis on intellectual property. We will face competition with respect to our current and future therapeutic product candidates from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization of products. Competition for improving plant genetics comes from conventional and advanced plant breeding techniques, as well as from the development of advanced biotechnology traits. Other potentially competitive sources of improvement in crop yields include improvements in crop protection chemicals, fertilizer formulations, farm mechanization, other biotechnology and information management. Programs to improve genetics and crop protection chemicals are generally concentrated within a relatively small number of large companies, while non-genetic approaches are underway with a broader set of companies.

There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we have research programs. Some of these competitive products and therapies are based on scientific approaches that are similar to our approach, and others are based on entirely different approaches. We principally compete with others developing and utilizing genome editing technology in the human health and plant sciences sectors, including companies such as Allogene Therapeutics, Inc., Alnylam Pharmaceuticals, Inc., Caribou Biosciences, Inc., Cellectis S.A., CRISPR Therapeutics, AG, Dicerna Pharmaceuticals, Inc., Editas Medicine, Inc., Intellia Therapeutics, Inc., Sangamo Therapeutics, Inc., and Beam Therapeutics, Inc. Several companies, including Novartis Pharmaceuticals Corp. and Gilead Sciences, Inc. have obtained FDA approval for autologous immunotherapies, and a number of companies, including Cellectis S.A., Celgene Corp., Allogene Therapeutics and CRISPR Therapeutics AG, are pursuing allogeneic immunotherapies. We expect that our operations focused on developing products for *in vivo* gene correction will face substantial competition from others focusing on gene therapy treatments, especially those that may focus on conditions that our product candidates target. Moreover, any human therapeutics products that we develop alone or with collaborators will compete with existing standards of care for the diseases and conditions that our product candidates target and other types of treatments, such as small molecule, antibody or protein therapies. Our competitors in the agricultural biotechnology space include Pairwise Plants, LLC, Corteva Agriscience, Tropic Biosciences UK LTD, Calyxt, Inc., Benson Hill Biosystems and Cibus.

Many of our current or potential competitors, either alone or with their collaborators, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical or greenhouse testing, conducting clinical or field trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and agricultural biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products we develop alone or with collaborators or that would render any such products obsolete or non-competitive. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we or our collaborators may obtain approval for any that we develop, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, technologies developed by our competitors may render our product candidates uneconomical or obsolete, and we or our collaborators may not be successful in marketing any product candidates we may develop against competitors. The availability of our competitors' products could limit the demand, and the price we are able to charge, for any products that we develop alone or with collaborators.

Our future profitability, if any, depends in part on our and our collaborators' ability to penetrate global markets, where we would be subject to additional regulatory burdens and other risks and uncertainties associated with international operations that could materially adversely affect our business.

Our future profitability, if any, will depend in part on our ability and the ability of our collaborators to commercialize any products that we or our collaborators may develop in markets throughout the world. Commercialization of products in various markets could subject us to risks and uncertainties, including:

- obtaining, on a country-by-country basis, the applicable marketing authorization from the competent regulatory authority;
- the burden of complying with complex and changing regulatory, tax, accounting, labor and other legal requirements in each jurisdiction that we or our collaborators pursue;

- reduced protection for intellectual property rights;
- differing medical and agricultural practices and customs affecting acceptance in the marketplace;
- import or export licensing requirements;
- governmental controls, trade restrictions or changes in tariffs;
- economic weakness, including inflation, or political instability in particular non-U.S. economies and markets;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers;
- foreign currency exchange rate fluctuations;
- foreign reimbursement, pricing and insurance regimes; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

We have limited or no prior experience in these areas, and our collaborators may have limited experience in these areas. Failure to successfully navigate these risks and uncertainties may limit or prevent market penetration for any products that we or our collaborators may develop, which would limit their commercial potential and our revenues.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any products that we develop alone or with collaborators.

We face an inherent risk of product liability and professional indemnity exposure related to the testing in clinical or field trials of our product candidates. We will face an even greater liability risk if we commercially sell any products that we or our collaborators may develop for human use or consumption. Manufacturing defects, errors in product distribution or storage processes, improper administration or application and known or unknown side effects of product usage may result in liability claims against us or third parties with which we have relationships. These actions could include claims resulting from acts by our collaborators, licensees and subcontractors over which we have little or no control.

For example, our liability could be sought by patients participating in clinical trials for potential therapeutic product candidates as a result of unexpected side effects, improper product administration or the deterioration of a patient's condition, patient injury or even death. Criminal or civil proceedings might be filed against us by patients, regulatory authorities, biopharmaceutical companies and any other third party using or marketing any product candidates or products that we develop alone or with collaborators. On occasion, large judgments have been awarded in class action lawsuits based on products that had unanticipated adverse effects. If we cannot successfully defend ourselves against claims that product candidates or products we develop alone or with collaborators caused harm, we could incur substantial liabilities.

Regardless of merit or eventual outcome, liability claims may result in:

- significant time and costs to defend the related litigation;
- injury to our reputation and significant negative media attention;
- diversion of management's attention from pursuing our strategy;
- withdrawal of clinical trial participants;
- delay or termination of clinical trials;
- decreased demand for any products that we develop alone or with collaborators;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue; and
- the inability to further develop or commercialize any products.

Although the clinical trial process is designed to identify and assess potential side effects, clinical development does not always fully characterize the safety and efficacy profile of a new medicine, and it is always possible that a drug or biologic, even after regulatory

approval, may exhibit unforeseen side effects. If our product candidates were to cause adverse side effects during clinical trials or after approval, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates. If any of our product candidates are approved for commercial sale, we will be highly dependent upon consumer perceptions of us and the safety and quality of such products. We could be adversely affected if we are subject to negative publicity associated with illness or other adverse effects resulting from patients' use or misuse of such products or any similar products distributed by other companies.

Although we maintain product liability insurance coverage, it may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage if we or our collaborators successfully commercialize any products. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liabilities to which we may become subject.

Additional Risks Related to the Identification, Development and Commercialization of Our Therapeutic Product Candidates

The regulatory landscape that will apply to development of therapeutic product candidates by us or our collaborators is rigorous, complex, uncertain and subject to change, which could result in delays or termination of development of such product candidates or unexpected costs in obtaining regulatory approvals.

Regulatory requirements governing products created with genome editing technology or involving gene therapy treatment have changed frequently and will likely continue to change in the future. Approvals by one regulatory agency may not be indicative of what any other regulatory agency may require for approval, and there has historically been substantial, and sometimes uncoordinated, overlap in those responsible for regulation of gene therapy products, cell therapy products and other products created with genome editing technology. For example, in the United States, the FDA has established the Office of Tissues and Advanced Therapies within its Center for Biologics Evaluation and Research ("CBER") to consolidate the review of gene therapy and related products, and the Cellular, Tissues, and Gene Therapies Advisory Committee to advise CBER on its review. Our product candidates will need to meet safety and efficacy standards applicable to any new biologic under the regulatory framework administered by the FDA.

In addition to the submission of an IND to the FDA, before initiation of a clinical trial in the United States, certain human clinical trials subject to the NIH Guidelines are subject to review and oversight by an institutional biosafety committee ("IBC"), a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment, and such review may result in some delay before initiation of a clinical trial. While the NIH Guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them. We are subject to significant regulatory oversight by the FDA, and in addition to the government regulators, the applicable IBC and institutional review board ("IRB") of each institution at which we or our collaborators conduct clinical trials of our product candidates, or a central IRB if appropriate, would need to review and approve the proposed clinical trial.

The same applies in the European Union ("EU"). The European Medicines Agency ("EMA") has a Committee for Advanced Therapies ("CAT") that is responsible for assessing the quality, safety and efficacy of advanced-therapy medicinal products. Advanced-therapy medical products include gene therapy medicine, somatic-cell therapy medicines and tissue-engineered medicines. The role of the CAT is to prepare a draft opinion on an application for marketing authorization for a gene therapy medicinal product candidate that is submitted to the EMA. In the EU, the development and evaluation of a gene therapy medicinal product must be considered in the context of the relevant EU guidelines. The EMA may issue new guidelines concerning the development and marketing authorization for gene therapy medicinal products and require that we comply with these new guidelines. Similarly complex regulatory environments exist in other jurisdictions in which we might consider seeking regulatory approvals for our product candidates, further complicating the regulatory landscape. As a result, the procedures and standards applied to gene therapy products and cell therapy products may be applied to any of our gene therapy or genome editing product candidates, but that remains uncertain at this point.

The clinical trial requirements of the FDA, the EMA and other regulatory authorities and the criteria these regulators use to evaluate the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for product candidates created with novel genome editing technology such as ours can be more lengthy, rigorous and expensive than the process for other better known or more extensively studied product candidates and technologies. Since we are developing novel treatments for diseases in which there is little clinical experience with new endpoints and methodologies, there is heightened risk that the FDA, the EMA or comparable regulatory bodies may not consider the clinical trial endpoints to provide clinically meaningful results, and the resulting clinical data and results may be more difficult to analyze. This may be a particularly significant risk for many of the genetically defined diseases for which we may develop product candidates alone or with collaborators due to small patient populations for those diseases, and designing and executing a rigorous clinical trial with appropriate statistical power is more difficult than with diseases that have larger patient populations. Regulatory agencies administering existing or future regulations or legislation may not allow production and marketing of products utilizing genome editing technology in a timely manner or under technically or commercially feasible conditions. Even if our product candidates obtain required regulatory approvals, such approvals may later be withdrawn as a result of changes in regulations or the interpretation of regulations by applicable regulatory agencies.

Changes in applicable regulatory guidelines may lengthen the regulatory review process for our product candidates, require additional studies or trials, increase development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of such product candidates, or lead to significant post-approval limitations or restrictions. Additionally, adverse developments in clinical trials conducted by others of gene therapy products or products created using genome editing technology, such as products developed through the application of a CRISPR/Cas9 technology, or adverse public perception of the field of genome editing, may cause the FDA, the EMA and other regulatory bodies to revise the requirements for approval of any product candidates we may develop or limit the use of products utilizing genome editing technologies, either of which could materially harm our business. Furthermore, regulatory action or private litigation could result in expenses, delays or other impediments to our research programs or the development or commercialization of current or future product candidates.

As we advance product candidates alone or with collaborators, we will be required to consult with these regulatory and advisory groups and comply with all applicable guidelines, rules and regulations. If we fail to do so, we or our collaborators may be required to delay or terminate development of such product candidates. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a product candidate to market could decrease our ability to generate sufficient product revenue to maintain our business.

We may not be able to submit INDs to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed.

We plan to submit INDs to enable us to conduct clinical trials for additional product candidates in the future, and we expect to file IND amendments to enable us to conduct additional clinical trials under existing INDs. We cannot be sure that submission of an IND or IND amendment will result in us being allowed to proceed with clinical trials, or that, once begun, issues will not arise that could result in the suspension or termination such clinical trials. The manufacturing of allogeneic CAR T cell therapy remains an emerging and evolving field. Accordingly, we expect chemistry, manufacturing and controls-related topics, including product specifications, will be a focus of IND reviews, which may delay receipt of authorization to proceed under INDs. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or clinical trial application, we cannot guarantee that such regulatory authorities will not change their requirements in the future.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

We and any collaborators are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining marketing approval from the FDA. Foreign regulatory authorities, such as the EMA, impose similar requirements. The time required to obtain approval by the FDA, the EMA and comparable foreign authorities is unpredictable, but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including substantial discretion of the regulatory authorities and sufficient resources at the FDA. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. To date, we have not submitted a biologics license application ("BLA") or other marketing authorization application to the FDA or similar drug approval submissions to comparable foreign regulatory authorities for any product candidate. We and any collaborators must complete additional preclinical or nonclinical studies and clinical trials to demonstrate the safety and efficacy of our product candidates in humans to the satisfaction of the regulatory authorities before we will be able to obtain these approvals.

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 or our collaborators' clinical trials;
- we or our collaborators 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 or our collaborators 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 or our collaborators' interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of product candidates may not be sufficient to support the submission of a BLA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we or our collaborators contract for clinical and commercial supplies;
- the FDA or comparable foreign regulatory authorities may fail to approve the companion diagnostics we may contemplate developing with collaborators; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our or our collaborators' clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may impose significant limitations in the form of narrow indications, warnings, or a Risk Evaluation and Mitigation Strategy ("REMS"). Regulatory authorities may not approve the price we or our collaborators intend to charge for products we may develop, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Clinical trials are difficult to design and implement, expensive, time-consuming and involve an uncertain outcome, and the inability to successfully and timely conduct clinical trials and obtain regulatory approval for our product candidates would substantially harm our business.

Clinical testing is expensive and usually takes many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process, and product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. We have initiated a Phase 1/2a clinical trial in patients with R/R NHL or R/R B-ALL, a Phase 1/2a clinical trial in subjects with NHL, chronic lymphocytic leukemia and small lymphocytic lymphoma, and a Phase 1/2a clinical trial in subjects with R/R multiple myeloma. We do not know whether any current or planned clinical trials will need to be redesigned, recruit and enroll patients on time or be completed on schedule, or at all. Clinical trials have been and may in the future be delayed, suspended or terminated for a variety of reasons, including in connection with:

- the inability to generate sufficient preclinical, toxicology or other *in vivo* or *in vitro* data to support the initiation of clinical trials;
- applicable regulatory authorities disagreeing as to the design or implementation of the clinical trials;
- obtaining regulatory authorization to commence a trial;
- reaching an agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining IRB approval at each site;
- developing and validating the companion diagnostic to be used in a clinical trial, if applicable;

- insufficient or inadequate supply or quality of product candidates or other materials, including identification of lymphocyte donors meeting regulatory standards necessary for use in clinical trials, or delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for clinical trials;
- recruiting and retaining enough suitable patients to participate in a trial;
- having enough patients complete a trial or return for post-treatment follow-up;
- adding a sufficient number of clinical trial sites;
- inspections of clinical trial sites or operations by applicable regulatory authorities, or the imposition of a clinical hold;
- clinical sites deviating from trial protocol or dropping out of a trial;
- the inability to demonstrate the efficacy and benefits of a product candidate;
- discovering that product candidates have unforeseen safety issues, undesirable side effects or other unexpected characteristics;
- addressing patient safety concerns that arise during the course of a trial;
- receiving untimely or unfavorable feedback from applicable regulatory authorities regarding the trial or requests from regulatory authorities to modify the design of a trial;
- non-compliance with applicable regulatory requirements by us or third parties or changes in such regulations or administrative actions;
- suspensions or terminations by IRBs of the institutions at which such trials are being conducted, by the Data Safety Monitoring Board ("DSMB") for such trial or by the FDA or other regulatory authorities due to a number of factors, including those described above;
- third parties being unable or unwilling to satisfy their contractual obligations to us;
- changes in our financial priorities, greater than anticipated costs of completing a trial or our inability to continue funding the trial; or
- unforeseen events, such as natural or manmade disasters, public health emergencies, such as the COVID-19 pandemic, which has and may continue to impact our operations, or other natural catastrophic events.

Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Additionally, we or our collaborators may experience unforeseen events during or resulting from clinical trials that could delay or prevent receipt of marketing approval for or commercialization of product candidates. For example, clinical trials of product candidates may produce negative, inconsistent or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon development programs. Regulators may also revise the requirements for approving the product candidates, or such requirements may not be as we anticipate. If we or our collaborators are required to conduct additional clinical trials or other testing of product candidates beyond those that we or our collaborators currently contemplate, if we or our collaborators are unable to successfully complete clinical trials or other testing of such product candidates, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- incur unplanned costs;
- be delayed in obtaining or fail to obtain marketing approval for product candidates;
- obtain marketing approval in some countries and not in others;
- obtain marketing approval for indications or patient populations that are not as broad as intended or desired;
- obtain marketing approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements;
- be subject to changes in the way the product is administered;
- have regulatory authorities withdraw or suspend their approval of the product or impose restrictions on its distribution;
- be sued; or
- experience damage to our reputation.

If we or our collaborators experience delays in the commencement or completion of our clinical trials, or if we or our collaborators terminate a clinical trial prior to completion, we may experience increased costs, have difficulty raising capital and/or be required to slow down the development and approval process timelines. Furthermore, the product candidates that are the subject of such trials may never receive regulatory approval, and their commercial prospects and our ability to generate product revenues from them could be impaired or not realized at all.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authorities may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authorities may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authorities, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

Any product candidates that we or our collaborators may develop will be novel and may be complex and difficult to manufacture, and if we experience manufacturing problems, it could result in delays in development and commercialization of such product candidates or otherwise harm our business.

Our product candidates involve or will involve novel genome editing technology and will require processing steps that are more complex than those required for most small molecule drugs, resulting in a relatively higher manufacturing cost. Moreover, unlike small molecules, the physical and chemical properties of biologics generally cannot be fully characterized. As a result, assays of the finished product may not be sufficient to ensure that such product will perform in the intended manner. Although we intend to employ multiple steps to control the manufacturing process, we may experience manufacturing issues with any of our product candidates that could cause production interruptions, including contamination, equipment or reagent failure, improper installation or operation of equipment, facility contamination, raw material shortages or contamination, natural disasters, disruption in utility services, human error, disruptions in the operations of our suppliers, inconsistency in cell growth and variability in product characteristics. We may encounter problems achieving adequate quantities and quality of clinical-grade materials that meet FDA, EMA or other comparable applicable standards or specifications with consistent and acceptable production yields and costs. For example, the FDA has required us to conduct testing of our allogeneic CAR T cell product candidates for the presence of certain human viruses prior to release of such products for clinical use. If the FDA concludes that further such viral testing of our product candidates is required and that any lots testing positive may not be used in clinical trials, we may need to produce new clinical trial materials, which could delay our clinical trials and result in higher manufacturing costs. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which such product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Our manufacturing process for any allogeneic CAR T cell product candidate that we develop alone or with collaborators will be susceptible to product loss or failure due to the quality of the raw materials, failure of the products to meet specifications, logistical issues associated with the collection of white blood cells, or starting material, from healthy third-party donors, shipping such material to the manufacturing site, ensuring standardized production batch-to-batch in the context of mass production, freezing the manufactured product, shipping the final product globally and infusing patients with such product. Problems with the manufacturing process, even minor deviations from the normal process, could result in product defects or manufacturing failures that result in lot failures, delays in initiating or completing clinical trials, product recalls, product liability claims or insufficient inventory.

As product candidates are developed through preclinical to late-stage clinical trials towards approval and commercialization, we expect that various aspects of the development program, such as manufacturing methods, may be altered along the way in an effort to help optimize processes and results. Such changes carry the risk that they will not achieve the intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of future clinical trials or our reliance on results of trials that have previously been conducted using the product candidate in its previous form. If the manufacturing process is changed during the course of product development, we or our collaborators may be required to repeat some or all of the previously conducted trials or conduct additional bridging trials, which could increase our costs and delay or impede our ability to obtain marketing approval.

We expect our manufacturing strategy for one or more of our product candidates may involve the use of CMOs as well as our newly opened manufacturing facility, MCAT. The facilities used by us and our contract manufacturers to manufacture therapeutic product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit a BLA to the FDA. We do not control the manufacturing process of our contract manufacturers and are dependent on their compliance with cGMP for their manufacture of our product candidates. We may establish multiple manufacturing facilities as we expand our commercial footprint to multiple geographies, which will be costly and time consuming and may lead to regulatory delays. Even if we are successful, our manufacturing capabilities could be affected by cost-overruns, potential problems with scale-out, process reproducibility, stability issues, lot inconsistency, timely availability of reagents or raw materials, unexpected delays, equipment failures, labor shortages,

natural disasters, utility failures, regulatory issues and other factors that could prevent us from realizing the intended benefits of our manufacturing strategy and have a material adverse effect on our business.

The FDA, the EMA and other foreign regulatory authorities may require us to submit samples of any lot of any product that may receive approval together with the protocols showing the results of applicable tests at any time. Under some circumstances, the FDA, the EMA or other foreign regulatory authorities may require that we not distribute a lot until the relevant agency authorizes its release. Slight deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. Lot failures or product recalls could cause us or our collaborators to delay product launches or clinical trials, which could be costly to us and otherwise harm our business. Problems in our manufacturing process also could restrict our or our collaborators' ability to meet market demand for products.

Any problems in our manufacturing process or facilities could make us a less attractive collaborator for potential partners, including larger pharmaceutical companies and academic research institutions, which could limit our access to additional attractive development opportunities.

We will rely on donors of T cells to manufacture product candidates from our allogeneic CAR T immunotherapy platform, and if we do not obtain an adequate supply of T cells from qualified donors, development of those product candidates may be adversely impacted.

We are developing a pipeline of allogeneic T cell product candidates that are engineered from healthy donor T cells, which vary in type and quality. This variability in type and quality of a donor's T cells makes producing standardized product candidates more difficult and makes the development and commercialization pathway of those product candidates more uncertain. We have developed a screening process designed to enhance the quality and consistency of T cells used in the manufacture of our CAR T cell product candidates. If we are unable to identify and obtain T cells from donors that satisfy our criteria in sufficient quantity, to obtain such cells in a timely manner or to address variability in donor T cells, development of our CAR T cell product candidates may be delayed or there may be inconsistencies in the product candidates we produce, which could negatively impact development of such product candidates, harm our reputation and adversely impact our business and prospects.

Failure to achieve operating efficiencies from MCAT may require us to devote additional resources and management time to manufacturing operations and may delay our product development timelines.

We have leased approximately 33,800 square feet of space for MCAT at a location approximately seven miles from our headquarters in Durham, North Carolina. We use this manufacturing center to create clinical trial material for certain of our current and planned clinical trials. We may not experience the anticipated operating efficiencies in our own manufacturing. Any delays in manufacturing may disrupt or delay the supply of our product candidates if we have not maintained a sufficient back-up supply of such product candidates through third-party manufacturers. Moreover, changing manufacturing facilities may also require that we or our collaborators conduct additional studies, make notifications to regulatory authorities, make additional filings to regulatory authorities, and obtain regulatory authority approval for the new facilities, which may be delayed or which we may never receive. We are also required to comply with the FDA's and applicable foreign regulatory authorities' cGMP requirements for the production of product candidates for clinical trials and, if approved, commercial supply, and will be subject to FDA and comparable foreign regulatory authority inspection. These requirements include the qualification and validation of our manufacturing equipment and processes. We may not be able to develop, acquire or maintain the internal expertise and resources necessary for compliance with these requirements. If we fail to achieve the operating efficiencies that we anticipate, our manufacturing and operating costs may be greater than expected, which could have a material adverse impact on our operating results.

We also may encounter problems hiring and retaining the experienced scientific, quality-control and manufacturing personnel needed to operate our manufacturing processes. If we experience unanticipated employee shortage or turnover in any of these areas, we may not be able to effectively manage our ongoing manufacturing operations and we may not achieve the operating efficiencies that we anticipate from the new facility, which may negatively affect our product development timeline or result in difficulties in maintaining compliance with applicable regulatory requirements.

Any such problems could result in the delay, prevention or impairment of clinical development and commercialization of our product candidates.

Any delays or difficulties in our or our collaborators ability to enroll patients in clinical trials, could delay or prevent receipt of regulatory approvals.

We or our collaborators may not be able to initiate or continue clinical trials on a timely basis or at all for any product candidates we or our collaborators identify or develop if we or our collaborators are unable to locate and enroll a sufficient number of eligible patients to participate in the trials as required by applicable regulations or as needed to provide appropriate statistical power for a given trial. Additionally, some of our competitors may have ongoing clinical trials for product candidates that would treat the same

indications as one or more of our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in our competitors' clinical trials.

Patient enrollment may also be affected by many factors, including:

- severity and difficulty of diagnosing of the disease under investigation;
- the difficulty in recruiting and/or identifying eligible patients suffering from rare diseases being evaluated under our trials;
- size of the patient population and process for identifying subjects;
- eligibility and exclusion criteria for the trial in question, including unforeseen requirements by the FDA or other regulatory authorities that we restrict one or more entry criteria for the study for safety reasons;
- our or our collaborators' ability to recruit clinical trial investigators with the appropriate competencies and experience;
- design of the trial protocol;
- availability and efficacy of approved medications or therapies, or other clinical trials, for the disease or condition under investigation;
- perceived risks and benefits of the product candidate under trial or testing, or of the application of genome editing to human indications;
- availability of genetic testing for potential patients;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- ability to obtain and maintain subject consent;
- risk that enrolled subjects will drop out before completion of the trial;
- ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients; and
- unforeseen events, such as natural or manmade disasters, public health emergencies, such as the COVID-19 pandemic which has and may continue to impact our operations, or other natural catastrophic events.

We expect that some of our product candidates will focus on rare genetically defined diseases with limited patient pools from which to draw for enrollment in clinical trials. The eligibility criteria of our clinical trials will further limit the pool of available trial participants. In addition to the factors identified above, patient enrollment in any clinical trials we or our collaborators may conduct may be adversely impacted by any negative outcomes our competitors may experience, including adverse side effects, clinical data showing inadequate efficacy or failures to obtain regulatory approval.

Furthermore, our or our collaborators' ability to successfully initiate, enroll and conduct a clinical trial outside the United States is subject to numerous additional risks, including:

- difficulty in establishing or managing relationships with CROs and physicians;
- differing standards for the conduct of clinical trials;
- differing standards of care for patients with a particular disease;
- an inability to locate qualified local consultants, physicians and partners; and
- the potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatments.

Enrollment delays in clinical trials, including those due to the COVID-19 pandemic, may result in increased development costs for any of our product candidates, which may cause the value of our company to decline and limit our ability to obtain additional financing. If we or our collaborators have difficulty enrolling a sufficient number of patients to conduct clinical trials as planned, we may need to delay, limit or terminate ongoing or planned clinical trials, any of which may have an adverse effect on our results of operations and prospects.

Results of preclinical studies and early clinical trials of product candidates may not be predictive of results of later studies or trials. Our product candidates may not have favorable results in later clinical trials, if any, or receive regulatory approval.

Preclinical and clinical drug development is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the preclinical study or clinical trial process. Despite promising preclinical or clinical results, any product candidate can unexpectedly fail at any stage of preclinical or clinical development. The historical failure rate for product candidates in our industry is high.

The results from preclinical studies or early clinical trials of a product candidate may not be predictive of the results from later preclinical studies or clinical trials, and interim results of a clinical trial are not necessarily indicative of final results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy characteristics despite having progressed through preclinical studies and initial clinical trials. Many companies in the biopharmaceutical and biotechnology industries have suffered significant setbacks at later stages of development after achieving positive results in early stages of development, and we may face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway or safety or efficacy observations made in clinical trials, including previously unreported adverse events. Moreover, non-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain regulatory approval. With the exception of our allogeneic anti-CD19, anti-CD20 and anti-BCMA CAR T product candidates, which have undergone limited testing in humans to date, our gene editing technology and our product candidates have never undergone testing in humans and have only been tested in a limited manner in animals, and results from animal studies may not be predictive of clinical trial results. Even if product candidates progress to clinical trials, these product candidates may fail to show the safety and efficacy in clinical development required to obtain regulatory approval, despite the observation of positive results in animal studies. Our or our collaborators' failure to replicate positive results from early research programs and preclinical or greenhouse studies may prevent us from further developing and commercializing those or other product candidates, which would limit our potential to generate revenues from them and harm our business and prospects.

For the foregoing reasons, we cannot be certain that any ongoing or future preclinical studies or clinical trials will be successful. Any safety or efficacy concerns observed in any one of our preclinical studies or clinical trials in a targeted area could limit the prospects for regulatory approval of product candidates in that and other areas, which could have a material adverse effect on our business and prospects.

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

From time to time, we may publish interim, initial or "top-line" data from preclinical or greenhouse studies or clinical or field trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line 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. Initial or "top-line" data also remain subject to audit and verification procedures that may result in the final data being materially different from these initial data we previously published. As a result, interim, initial and "top-line" data should be viewed with caution until the final data are available.

Additionally, interim data from clinical trials that we may complete 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 initial or interim data and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed significant by you or others with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the top-line 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, product candidates may be harmed, which could significantly harm our business prospects.

Our product candidates may not work as intended or cause undesirable side effects that, could hinder or prevent receipt of regulatory approval or realization of commercial potential for them or our other product candidates and substantially harm our

business.

Our product candidates may be associated with off-target editing or other serious adverse events, undesirable side effects or unexpected characteristics. Results of clinical trials could reveal severe or recurring side effects, toxicities or unexpected events, including death. Off-target cuts could lead to disruption of a gene or a genetic regulatory sequence at an unintended site in the DNA. In those instances where we also provide a segment of DNA, it is possible that following off-target cut events, such DNA could be integrated into the genome at an unintended site, potentially disrupting another important gene or genomic element. There may also be delayed adverse events following exposure to therapeutics made with genome editing technologies due to persistent biologic activity of the genetic material or other components of products used to carry the genetic material. In addition to serious adverse events or side effects caused by product candidates we develop alone or with collaborators, the administration process or related procedures may also cause undesirable side effects. For example, one NHL patient in our Phase 1/2a clinical trial who was treated with PBCAR0191 and eLD suffered episodes of sepsis, which resulted in a fatal outcome.

Further, any side effects may not be appropriately recognized or managed by the treating medical staff. We or our collaborators expect to have to educate medical personnel using any product candidates we may develop to understand the side effect profiles for our clinical trials and upon any commercialization of such product candidates. Inadequate recognition or management of the potential side effects of such product candidates could result in patient injury or death.

If any such events occur, clinical trials or commercial distribution of any product candidates or products we develop alone or with collaborators could be suspended or terminated, and our business and reputation could suffer substantial harm. Treatment-related side effects could affect patient recruitment and the ability of enrolled patients to complete the trial or result in potential liability claims. Regulatory authorities could order us or our collaborators to cease further development of, deny approval of or require us to cease selling any product candidates or products for any or all targeted indications. If we or our collaborators elect, or are required, to delay, suspend or terminate any clinical trial or commercialization efforts, the commercial prospects of such product candidates or products may be harmed, and our ability to generate product revenues from them or other product candidates that we develop may be delayed or eliminated.

Additionally, if we successfully develop a product candidate alone or with collaborators and it receives marketing approval, the FDA could require us to adopt a REMS to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry. We or our collaborators may also be required to adopt a REMS or engage in similar actions, such as patient education, certification of health care professionals or specific monitoring, if we or others later identify undesirable side effects caused by any product that we develop alone or with collaborators. Such identification could also have several additional significant negative consequences, such as:

- regulatory authorities may suspend, withdraw or limit approvals of such product, or seek an injunction against its manufacture or distribution;
- regulatory authorities may require additional warnings on the label, including “boxed” warnings, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way a product is administered or conduct additional trials;
- the product may become less competitive;
- we or our collaborators may decide to remove the product from the marketplace;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- we could be sued and be held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us or our collaborators from achieving or maintaining market acceptance of any potential product, or otherwise have a negative impact on our business.

We are subject to federal, state and non-U.S. healthcare laws and regulations relating to our business, and could face substantial penalties if we are determined not to have fully complied with such laws, which would have an adverse impact on our business.

Our business operations, as well as our current and anticipated future arrangements with investigators, healthcare professionals, consultants, third-party payors, customers and patients, expose or will expose us to broadly applicable foreign, federal, and state fraud

and abuse and other healthcare laws and regulations. These laws constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute any potential products for which we may obtain marketing approval. Such laws include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a U.S. healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the U.S. federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation;

- U.S. federal civil and criminal false claims laws, including the civil False Claims Act, which can be enforced through civil whistleblower or qui tam actions, and civil monetary penalties laws, prohibits, among other things, individuals and entities from knowingly presenting, or causing to be presented, to the U.S. government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. government. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- the U.S. 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, including private third-party payors, 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 U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the U.S. Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other health care professionals beginning in 2022, and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the Centers for Medicare and Medicaid Services ("CMS"), ownership and investment interests held by the physicians described above and their immediate family members; and

- analogous state and non-U.S. laws and regulations, such as state anti-kickback and anti-corruption and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or by the patients themselves; state laws and non-U.S. laws and regulations that require pharmaceutical and device companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. government or foreign governmental authorities, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and local laws and regulations and non-U.S. laws and regulations that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; state and local laws and non-U.S. laws and regulations which require the registration of pharmaceutical sales representatives.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities may conclude that our business practices, including our relationships with certain physicians, some of whom are compensated in the form of stock options for consulting services provided, do not comply with current or future statutes, regulations, agency guidance or case law involving applicable healthcare laws. If our operations are found to be in violation of any of these or any other health regulatory laws that may apply to us, we may be subject to significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other U.S. or foreign healthcare programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Defending against any such actions can be costly, time-consuming and may require significant financial and 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. If any of the above occur, it could adversely affect our ability to operate our business and our results of operations.

Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements, and the increasing use of social media, could adversely affect our business, results of operations, and financial condition.

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, use, disclosure, retention, and security of personal data, such as information that we may collect in connection with clinical trials in the U.S. and abroad. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards can be high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulation, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our operations, financial performance and business.

As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. In the U.S., HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (“HITECH”) and their implementing regulations, imposes, among other things, certain standards relating to the privacy, security, transmission and breach reporting of individually identifiable health information on covered entities (defined as health plans, health care clearinghouses and certain health care providers) and their respective business associates, individuals or entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HIPAA mandates the reporting of certain breaches of health information to HHS, affected individuals and if the breach is large enough, the media. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured protected health information, a complaint about privacy practices or an audit by HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. Even when HIPAA does not apply, according to the Federal Trade Commission or the FTC, failing to take appropriate steps to keep consumers’ personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act. The FTC expects a company’s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards.

Certain states have also adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. In addition, California recently enacted the California Consumer Privacy Act (“CCPA”), which went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Further, the California Public Records Act (“CPRA”), recently passed in California. The CPRA will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the CPRA provisions are expected to go into effect on January 1, 2023. The CCPA, and the CPRA, may increase our compliance costs and potential liability, and many similar laws have been proposed at the federal level and in other states. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

In Europe, the GDPR, went into effect in May 2018 and introduces strict requirements for processing the personal data of individuals within the EEA. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements. From January 1, 2021 we are subject to compliance with the GDPR and the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, i.e., fines up to the greater of €20 million/ £17 million or 4% of global turnover. The relationship between the UK and the EU in relation to certain aspects of data protection law remains unclear, and it is unclear how UK data protection laws and regulations will develop in the medium to longer term, and how data transfers between EU member states will be regulated in the long run. Currently there is a four- to six-month grace period agreed in the EU and UK Trade and Cooperation Agreement, ending June 30, 2021 at the latest, whilst the parties discuss an adequacy decision. However, it is not clear whether (and when) an adequacy decision may be granted by the European Commission enabling data transfers from EU member states to the UK long term without additional measures. These changes will lead to additional costs and increase our overall risk exposure.

Recent legal developments in Europe have created complexity and uncertainty regarding transfers of personal data from the EEA and the UK to the U.S. Most recently, on July 16, 2020, the Court of Justice of the European Union ("CJEU") invalidated the EU-US Privacy Shield Framework, the Privacy Shield, under which personal data could be transferred from the EEA to US entities who had self-certified under the Privacy Shield scheme. While the CJEU upheld the adequacy of the standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism, and potential alternative to the Privacy Shield), it made clear that reliance on them alone may not necessarily be sufficient in all circumstances. Use of the standard contractual clauses must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals and additional measures and/or contractual provisions may need to be put in place, however, the nature of these additional measures is currently uncertain. The CJEU went on to state that if a competent supervisory authority believes that the standard contractual clauses cannot be complied with in the destination country and the required level of protection cannot be secured by other means, such supervisory authority is under an obligation to suspend or prohibit that transfer.

These recent developments may require us to review and amend the legal mechanisms by which we make and/ or receive personal data transfers to/ in the U.S. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the standard contractual clauses cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

Despite our efforts to monitor evolving social media communication guidelines and comply with applicable rules, there is risk that the use of social media by us or our employees to communicate about our product candidates or business may cause us to be found in violation of applicable requirements. In addition, our employees may knowingly or inadvertently make use of social media in ways that may not comply with our internal policies or other legal or contractual requirements, which may give rise to liability, lead to the loss of trade secrets or other intellectual property, or result in public exposure of personal information of our employees, clinical trial patients, customers and others. Our potential patient population may also be active on social media and use these platforms to comment on the effectiveness of, or adverse experiences with, our product candidates. Negative posts or comments about us or our product candidates on social media could seriously damage our reputation, brand image and goodwill.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, CROs, collaborators, or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation, and adversely affect our business and results of operations.

We have received orphan drug designation for PBCAR0191 for the treatment of ALL and mantle cell lymphoma PBCAR20A for the treatment of MCL, and PBCAR269A for the treatment of multiple myeloma, and we may seek orphan drug designation for some or all of our other product candidates, but we may be unable to obtain such designations or to maintain the benefits associated with orphan drug designation, which may negatively impact our ability to develop or obtain regulatory approval for such product candidates and may reduce our revenue if we obtain such approval.

We may seek orphan drug designation for some or all of our product candidates in specific orphan indications in which there is a medically plausible basis for the use of these products. Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting a BLA. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax

advantages and user-fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. Although we may seek orphan product designation for some or all of our other product candidates, we may never receive such designations.

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a BLA, to market the same biologic for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan product exclusivity or if FDA finds that the holder of the orphan drug exclusivity has not shown that it can ensure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Even if we or our collaborators obtain orphan drug designation for a product candidate, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products. Exclusive marketing rights in the United States may be limited if we or our collaborators seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if a product obtains orphan drug exclusivity, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is safer, more effective, or makes a major contribution to patient care. Furthermore, the FDA can waive orphan exclusivity if we or our collaborators are unable to manufacture sufficient supply of the product.

Similarly, in the EU, a medicinal product may receive orphan designation under Article 3 of Regulation (EC) 141/2000. This applies to products that are intended for a life-threatening or chronically debilitating condition and either (1) such condition affects not more than five in 10,000 persons in the EU when the application is made, or (2) the product, without the benefits derived from orphan status, would be unlikely to generate sufficient returns in the EU to justify the necessary investment. Moreover, in order to obtain orphan designation in the EU it is necessary to demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU or, if such a method exists, the product will be of significant benefit to those affected by the condition. In the EU, orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and applicants can benefit from specific regulatory assistance and scientific advice. Products receiving orphan designation in the EU can receive 10 years of market exclusivity, during which time no similar medicinal product for the same indication may be placed on the market. An orphan product can also obtain an additional two years of market exclusivity in the EU for pediatric studies. However, the 10-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation—for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization may be granted to a similar product for the same indication at any time if:

- the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior;
- the first applicant consents to a second orphan medicinal product application; or
- the first applicant cannot supply enough orphan medicinal product.

If we or our collaborators do not receive or maintain orphan drug designation for product candidates for which we seek such designation, it could limit our ability to realize revenues from such product candidates.

We have received and may continue to seek fast track designation, and may seek breakthrough therapy designation, Regenerative Medicine Advanced Therapy ("RMAT") designation, or priority review from the FDA or access to the PRIME scheme from the EMA for some or all of our product candidates, but we may not receive such designations, and even if we do, it may not lead to a faster development or regulatory review or approval process, and will not increase the likelihood that such product candidates will receive marketing approval.

We have received fast track designation for PBCAR0191 for the treatment of B-ALL as well as PBCAR269A for R/R multiple myeloma. We may continue to seek fast track designation and may also seek breakthrough therapy designation, RMAT designation or priority review from the FDA, or access to the PRIME scheme from the EMA for some or all of our product candidates. If a drug is intended for the treatment of a serious or life-threatening condition or disease, and nonclinical or clinical data demonstrate the potential to address an unmet medical need, the product may qualify for FDA fast track designation, for which sponsors must apply. The FDA has broad discretion whether or not to grant this designation. If granted, fast track designation makes a drug eligible for more frequent interactions with FDA to discuss the development plan and clinical trial design, as well as rolling review of the application, which means that the company can submit completed sections of its marketing application for review prior to completion of the entire submission. Products with fast track designation may also be eligible for accelerated approval and priority review, if the relevant criteria are met.

Breakthrough therapy designation is intended to expedite the development and review of product candidates that treat serious or life-threatening diseases when "preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development." The designation of a product candidate as a breakthrough therapy provides the same potential benefits as a fast track designation, with more intensive FDA guidance on an efficient development program and an organizational commitment at FDA involving senior managers.

A company may also request RMAT designation of its product candidate, which designation may be granted if the drug meets the following criteria: (1) it qualifies as a RMAT, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; (2) it is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (3) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition. Like breakthrough therapy designation, RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate, and potential eligibility for rolling review and priority review. Products granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites. RMAT- designated products that receive accelerated approval may, as appropriate, fulfill their post-approval requirements through the submission of clinical evidence, clinical studies, patient registries, or other sources of real world evidence (such as electronic health records); through the collection of larger confirmatory data sets; or via post-approval monitoring of all patients treated with such therapy prior to approval of the therapy.

PRIME is a scheme provided by the EMA to enhance support for the development of medicines that target an unmet medical need. To qualify for PRIME, product candidates require early clinical evidence that the therapy has the potential to offer a therapeutic advantage over existing treatments or benefits patients without treatment options. Among the benefits of PRIME are the appointment of a rapporteur to provide continuous support and help build knowledge ahead of a marketing authorization application, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review earlier in the application process.

Based on legislation adopted late in 2007, the EMA established an additional regulatory designation for products classified as an advanced therapy medicinal product (ATMP). The ATMP classification offers sponsors a variety of benefits similar to those associated with the PRIME scheme, including scientific and regulatory guidance, additional opportunities for dialogue with regulators, and presubmission review and certification of the CMC and nonclinical data proposed for submission in a forthcoming MA applications for micro-, small-, or medium-sized enterprises. To qualify for this designation, product candidates intended for human use must be based on gene therapy, somatic cell therapy, or tissue engineered therapy (i.e., engineered cells or tissues intended to regenerate, replace or repair human tissue).

There is no assurance that we will obtain additional fast track designation, or that we will obtain breakthrough therapy designation, RMAT designation or access to PRIME or ATMP for any of our product candidates. Fast track designation, breakthrough therapy designation, RMAT designation and PRIME and ATMP eligibility do not change the standards for product approval, and there is no assurance that any such designation or eligibility will result in expedited review or approval or that the approved indication will not be narrower than the indication covered by the fast track designation, breakthrough therapy designation, RMAT designation or PRIME or ATMP eligibility. Additionally, fast track designation, breakthrough therapy designation, RMAT designation and access to PRIME or ATMP can each be revoked if the criteria for eligibility cease to be met as clinical data emerges.

If the product candidates that we or our collaborators may develop receive regulatory approval in the United States or another jurisdiction, they may never receive approval in other jurisdictions, which would limit market opportunities for such product candidate and adversely affect our business.

Approval of a product candidate in the United States by the FDA or by the requisite regulatory agencies in any other jurisdiction does not ensure approval of such product candidate by regulatory authorities in other countries or jurisdictions. The approval process varies among countries and may limit our or our collaborators' ability to develop, manufacture, promote and sell product candidates internationally. Failure to obtain marketing approval in international jurisdictions would prevent the product candidates from being marketed outside of the jurisdictions in which regulatory approvals have been received. In order to market and sell product candidates in the EU and many other jurisdictions, we and our collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and may involve additional preclinical studies or clinical trials both before and after approval. In many countries, any product candidate for human use must be approved for reimbursement before it can be approved for sale in that country. In some cases, the intended price for such product is also subject to approval. Further, while regulatory approval of a product candidate in one country does not ensure approval in any other country, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. If we or our collaborators fail to comply with the regulatory requirements in international markets or to obtain all required

marketing approvals, the target market for a particular potential product will be reduced, which would limit our ability to realize the full market potential for the product and adversely affect our business.

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

In the United States and certain non-U.S. jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our or our collaborators' ability to profitably sell any product candidates that obtain marketing approval.

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively the Affordable Care Act, was enacted in the United States. Among the provisions of the Affordable Care Act of importance to our product candidates, the Affordable Care Act established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations, expanded eligibility criteria for Medicaid programs, expanded the entities eligible for discounts under the Public Health program, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, created a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D, and created a licensure framework for follow-on biologic products.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the Affordable Care Act. The U.S. Supreme Court is currently reviewing the constitutionality of the Affordable Care Act in its entirety, although it is unclear when or how the Supreme Court will rule.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, included reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through December 31, 2021, unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, there has been heightened governmental scrutiny recently over pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies, rebates and price negotiation for pharmaceutical products. The probability of success of any previously announced policies under the Trump administration and their impact on the United States prescription drug marketplace is unknown, particularly in light of the Biden administration. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product and medical device pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and medical devices to purchase and which suppliers will be included in their prescription drug and other healthcare programs.

We expect that other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria, new payment methodologies and in additional downward pressure on the price that we or our collaborators may receive for any approved or cleared product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we or our collaborators are slow or unable to adapt to new requirements or policies, or if we or our collaborators are not able to maintain regulatory compliance, any of our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

Even if we obtain regulatory approval for any products that we develop alone or with collaborators, such products will remain subject to ongoing regulatory requirements, which may result in significant additional expense.

Even if products we develop alone or with collaborators receive regulatory approval, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, distribution, storage, advertising, promotion, sampling, record-keeping and submission of safety and other post-market information, among other things. Any regulatory approvals received for such products may also be subject to limitations on the approved indicated uses for which they may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing and surveillance studies. For example, the holder of an approved BLA in the United States is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. FDA guidance advises that patients treated with some types of gene therapy undergo follow-up observations for potential adverse events for as long as 15 years. Similarly, in the EU, pharmacovigilance obligations are applicable to all medicinal products. In addition to those, holders of a marketing authorization for gene or cell therapy products must detail, in their application, the measures they envisage to ensure follow-up of the efficacy and safety of these products. In cases of particular concern, marketing authorization holders for gene or cell therapy products in the EU may be required to design a risk management system with a view to identifying, preventing or minimizing risks and may be obliged to carry out post-marketing studies. In the United States, the holder of an approved BLA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Similar provisions apply in the EU. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws. Similarly, in the EU any promotion of medicinal products is highly regulated and, depending on the specific jurisdiction involved, may require prior vetting by the competent national regulatory authority.

In addition, product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements and adherence to commitments made in the BLA or foreign marketing application. If we, our collaborators or 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 that product, a regulatory agency may impose restrictions relative to that product, the manufacturing facility or us or our collaborators, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

Moreover, if any of our product candidates are approved, our product labeling, advertising, promotion and distribution will be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about drug products. 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 or our collaborators fail to comply with applicable regulatory requirements following approval of any potential products we may develop, authorities may:

- issue an untitled enforcement letter or a warning letter asserting a violation of the law;
- seek an injunction, impose civil and criminal penalties, and impose monetary fines, restitution or disgorgement of profits or revenues;
- suspend or withdraw regulatory approval;
- suspend or terminate any ongoing clinical trials or implement requirements to conduct post-marketing studies or clinical trials;
- refuse to approve a pending BLA or comparable foreign marketing application (or any supplements thereto) submitted by us or our collaborators;
- restrict the labeling, marketing, distribution, use or manufacturing of products;
- seize or detain products or otherwise require the withdrawal or recall of products from the market;
- refuse to approve pending applications or supplements to approved applications that we or our collaborators submit;
- refuse to permit the import or export of products; or
- refuse to allow us or our collaborators to enter into government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our or our collaborators' ability to commercialize products and our ability to generate revenues.

In addition, the FDA's policies, and policies of foreign regulatory agencies, may change, and additional regulations may be enacted that could prevent, limit or delay regulatory approval of product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, the results of the 2020 Presidential election and recent change in administration may impact our business and industry. The Trump administration, for example, took several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance and review and approval of marketing applications. It is difficult to predict whether or how these requirements will be implemented or whether they will be rescinded or replaced under the Biden Administration. The policies and priorities of the Biden administration are unknown and could materially impact the regulation governing our products. If we or our collaborators are slow or unable to adapt to changes in existing requirements or the adoption of new requirements, or if we or our collaborators are unable to maintain regulatory compliance, marketing approval that has been obtained may be lost and we may not achieve or sustain profitability.

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

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

Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products. Subsequently, on March 18, 2020 the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Additionally, on April 15, 2021, the FDA issued a guidance document in which the FDA described its plans to conduct voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites. According to the guidance, the FDA intends to request such remote interactive evaluations in situations where an in-person inspection would not be prioritized, deemed mission-critical, or where direct inspection is otherwise limited by travel restrictions, but where the FDA determines that remote evaluation would be appropriate. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Even if any product we develop alone or with collaborators receives marketing approval, such product may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

The commercial success of any potential therapeutic products we develop alone or with collaborators will depend upon their degree of market acceptance by physicians, patients, third-party payors and others in the medical community. Even if any potential therapeutic products we develop alone or with collaborators receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. The degree of market acceptance of any product we develop alone or with collaborators, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of such product as demonstrated in clinical trials;
- the prevalence and severity of any side effects;
- the clinical indications for which the product is approved by FDA, the EMA or other regulatory authorities;

- product labeling or product insert requirements of the FDA, the EMA or other regulatory authorities, including any limitations or warnings contained in a product's approved labeling;
- public attitudes regarding genome editing technologies;
- our and any collaborators' ability to educate the medical community about the safety and effectiveness of the product;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies, as well as their willingness to accept a therapeutic intervention that involves the editing of the patient's genome;
- the potential and perceived advantages compared to alternative treatments;
- convenience and ease of administration compared to alternative treatments;
- any restrictions on the use of such product together with other treatments or products;
- market introduction of competitive products;
- publicity concerning such product or competing products and treatments;
- the ability to offer such product for sale at a competitive price;
- the strength of marketing and distribution support; and
- sufficient third-party coverage and adequate reimbursement.

If any products we develop alone or with collaborators do not achieve an adequate level of acceptance, we may not generate significant product revenues, and we may not become profitable.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any products we develop alone or with collaborators, the commercialization of such products may not be successful if and when they are approved.

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of biopharmaceutical or other commercial products. To achieve commercial success for any approved products for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization or outsource these functions to third parties. In the future, we may choose to build a focused sales, marketing and commercial support infrastructure to sell, or participate in sales activities with our collaborators for, certain product candidates if and when they are approved.

There are risks involved with both establishing our own commercial capabilities and entering into arrangements with third parties to perform these services. For example, restricted or closed distribution channels may make it difficult to distribute products to segments of the patient population, and the lack of complementary medicines to be offered by sales personnel may put us at a competitive disadvantage relative to companies with more extensive product lines.

Recruiting and training a sales force or reimbursement specialists are expensive and time consuming and could delay any product launch. If the commercial launch of a product for which we recruit a sales force and establish marketing and other commercialization capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses, and our investment would be lost if we cannot retain or reposition our commercialization personnel. Factors that may inhibit our efforts to commercialize products on our own include:

- unforeseen costs and expenses associated with creating an independent commercialization organization;
- our inability to recruit, train, retain and effectively manage adequate numbers of effective sales, marketing, customer service and other support personnel, including for reimbursement or medical affairs;
- the inability of sales personnel to educate adequate numbers of physicians on the benefits of our future medicines; and
- the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement and other acceptance by payors.

If we choose to enter into arrangements with third parties to perform sales, marketing, commercial support or distribution services, we may not be successful in entering into such arrangements or may be unable to do so on terms that are favorable to us. Entering into such third-party arrangements may subject us to a variety of risks, including:

- product revenues or profitability to us being lower than if we were to market and sell any products we or our collaborators may develop ourselves;
- our inability to exercise direct control over sales and marketing activities and personnel;

- failure of the third parties to devote necessary resources and attention to, or other inability to, sell and market any products we or our collaborators may develop;
- potential disputes with third parties concerning sales and marketing expenses, calculation of royalties and sales and marketing strategies; and
- unforeseen costs and expenses associated with sales and marketing.

If we do not establish effective commercialization capabilities, either on our own or in collaboration with third parties, we will not be successful in commercializing any of our product candidates that may receive approval.

If the market opportunities for any products we develop alone or with collaborators are smaller than our estimates, or if we are unable to successfully identify enough patients, our revenues may be adversely affected.

We focus some of our research and product development on treatments for rare genetic diseases. Our and our collaborators' projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with product candidates we may develop, are based on estimates. These estimates may prove to be incorrect, and new studies may change the estimated incidence or prevalence of these diseases. The number of patients in the United States, Europe and elsewhere may turn out to be lower than expected, and patients may not be amenable to treatment with products that we may develop alone or with collaborators, or may become increasingly difficult to identify or gain access to, any of which would decrease our ability to realize revenue from any such products for such diseases.

The successful commercialization of potential products will depend in part on the extent to which governmental authorities and health insurers establish coverage, and the adequacy of reimbursement levels and pricing policies, and failure to obtain or maintain coverage and adequate reimbursement for any potential products that may receive approval, could limit marketability of those products and decrease our ability to generate revenue.

The availability of coverage and adequacy of reimbursement by government healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors is essential for most patients to be able to afford prescription medications such as the potential therapeutic products we develop alone or with collaborators. The ability to achieve acceptable levels of coverage and reimbursement for any potential products that may be approved by governmental authorities will have an effect on our and our collaborators' ability to successfully commercialize such products. Even if products we develop alone or with collaborators obtain coverage by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. If coverage and reimbursement in the United States, the EU or elsewhere is not available for any products we develop alone or with collaborators that may be approved, or any reimbursement that may become available is decreased or eliminated in the future, we and our collaborators may be unable to commercialize such products.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved drugs and biologics. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered. In August 2019, the CMS published its decision to cover autologous treatment for cancer with T-cells expressing at least one CAR when administered at healthcare facilities enrolled in the FDA risk evaluation and mitigation strategies and used for an FDA-approved indication or for other uses when the product has been FDA-approved and the use is supported in one or more CMS-approved compendia. The Medicare and Medicaid programs increasingly are used as models in the United States for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. We cannot predict at this time what third-party payors will decide with respect to the coverage and reimbursement for any product that we develop alone or with collaborators.

No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us or our collaborators to provide scientific and clinical support for the use of any potential products that may be approved to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice. Obtaining coverage and adequate reimbursement for products we develop alone or with collaborators may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. In certain instances, payors may not separately reimburse for the product itself, but only for the treatments or procedures in which such product is used. A decision by a third-party payor not to cover or separately reimburse for products that we develop alone or with collaborators or procedures using such products, could reduce physician utilization of any such products that may receive approval.

Third-party payors are increasingly challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs or biologics when an equivalent generic drug, biosimilar or a less expensive therapy is available. If approved, it is possible that a third-party payor may consider any products that we develop alone or with collaborators as substitutable and only offer to reimburse patients for the less expensive product. Pricing of existing third-party therapeutics may limit the amount we will be able to charge for any products that may receive approval even if we or our collaborators show improved efficacy or improved convenience of administration such products. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in the product. If reimbursement is not available or is available only at limited levels, we or our collaborators may not be able to successfully commercialize any of the products that we develop, even if approved, and we may not be able to obtain a satisfactory financial return on them. Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for any products we develop alone or with collaborators that may receive approval. We expect to experience pricing pressures in connection with the sale of any products that may receive approval due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and biologics and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and elsewhere have and will continue to put pressure on the pricing and usage of any products we develop alone or with collaborators that may receive approval. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Additional international price controls or other changes in pricing regulation could restrict the amount that we or our collaborators are able to charge for products that we develop that may receive approval. Accordingly, in markets outside the United States, the reimbursement for such products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

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

If we are successful in achieving regulatory approval to commercialize any biologic product candidate we develop alone or with collaborators, it may face competition from biosimilar products. In the United States, our product candidates are regulated by the FDA as biologic products subject to approval under the BLA pathway. The Biologics Price Competition and Innovation Act of 2009 (“BPCIA”) created an abbreviated pathway for the approval of biosimilar and interchangeable biologic products following the approval of an original BLA. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as “interchangeable” based on its similarity to an existing brand product. Under the BPCIA, an application for a biosimilar product may not be submitted until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years after the reference product was first licensed by the FDA. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor’s own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty.

We believe that any of our product candidates that are approved as biological products 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 such product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. If competitors are able to obtain marketing approval for biosimilars referencing any products that we develop alone or with collaborators that may be approved, such products may become subject to competition from such biosimilars, with the attendant competitive pressure and potential adverse consequences.

Additional Risks Related to the Identification, Development and Commercialization of Our Food and Agricultural Product Candidates

The regulatory landscape that may govern any potential food or agricultural products that we or our collaborators may develop is uncertain and may adversely impact the development and commercialization activities of our food platform.

In the United States, the United States Department of Agriculture (“USDA”) regulates, among other things, the introduction (including the importation, interstate movement or release into the environment) of organisms and products altered or produced through genetic engineering determined to be plant pests or for which there is reason to believe are plant pests. Such organisms and products are considered “regulated articles.” However, a petitioner may submit a request for a determination by the USDA of “nonregulated status”

for a particular article. A petition for determination of nonregulated status must include detailed information, including relevant experimental data and publications, field trial reports and a description of the genotypic differences between the regulated article and the non-modified recipient organism, among other things. Neither we nor, to our knowledge, our collaborators have obtained a determination from the USDA that any product candidates are not "regulated articles" under these regulations. We cannot predict whether the USDA, advocacy groups or other third parties will contend that these products are regulated articles. The USDA's regulations also require that companies obtain a permit or file a notification before engaging in the introduction (including the importation, interstate movement or release into the environment such as in field trials) of "regulated articles." Additionally, a change in the way the USDA interprets its regulations, or a change in its regulations, could subject our or our collaborators' products to more burdensome regulations, thereby substantially increasing the time and costs associated with developing product candidates. Complying with the USDA's Part 340 regulations, including permitting requirements, is a costly, time-consuming process and could delay or prevent the commercialization of any potential food or agricultural products we or our collaborators may develop.

Any potential food or agricultural products that we or our collaborators develop may also be subject to extensive FDA food product regulations. Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act ("FDCA") any substance that becomes or is reasonably expected to become a component of food is a food additive and is therefore subject to FDA premarket review and approval, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use (generally recognized as safe, or GRAS), or unless the use of the substance is otherwise excluded from the definition of a food additive, and any food that contains an unsafe food additive is considered adulterated under section 402(a)(2)(C) of the FDCA. The FDA may classify some or all of the potential food or agricultural products that we or our collaborators may develop as containing a food additive that is not GRAS or otherwise determine that such products contain significant compositional differences from existing plant products that require further review. Such classification would cause these potential products to require pre-market approval, which could delay the commercialization of these products. In addition, the FDA is currently evaluating its approach to the regulation of gene-edited plants. For example, on January 19, 2017, the FDA issued a notice in the Federal Register requesting public comment on the use of genome editing techniques to produce new plant varieties that are used for human or animal food or foods that are derived from such new plant varieties produced using genome editing. Among other things, the notice asked for data and information in response to questions about the safety of foods from gene-edited plants, such as whether categories of gene-edited plants present food safety risks different from other plants produced through traditional plant breeding. If the FDA enacts new regulations or policies with respect to gene-edited plants, such policies could result in additional compliance costs and delay or even prevent the commercialization of any of our product candidates, which could negatively affect our profitability. Any delay in the regulatory consultation process, or a determination that any potential products we or our collaborators may develop do not meet regulatory requirements by the FDA or other regulators, could cause a delay in, or prevent, the commercialization of our products, which may lead to reduced acceptance by the public and an increase in competitor products that may directly compete with ours, or could otherwise negatively impact our business, prospects and results of operations.

On December 21, 2018, the USDA finalized a rule implementing the National Bioengineered Food Disclosure Standard, with an implementation date of January 1, 2020. Under this rule, the label of a bioengineered ("BE") food must include a disclosure that the food is a BE food or contains a BE ingredient, with certain exceptions. This rule defines BE food as "a food that contains genetic material that was has been modified through in vitro recombinant deoxyribonucleic acid ("DNA") techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature," except in the case of an incidental additive present in food at an insignificant level and that does not have any technical or functional effect in the food. Under this rule, products developed by our collaborators based on our ARCUS technology may be required to be labeled "BE," in which case consumer perception of these products may be adversely affected.

In the European Economic Area, or EEA (which is comprised of the 27 Member States of the European Union, or EU, plus Norway, Liechtenstein, and Iceland), genetically modified foods ("GM foods") can only be authorized for sale on the market once they have been subject to rigorous safety assessments. The procedures for evaluation and authorization of GM foods are notably governed by Regulation (EC) 1829/2003 on GM food and feed and Directive 2001/18/EC (as amended and transposed into EEA member states' law and regulations) on the release of GMOs into the environment. If the GMO is not to be used in food or feed, then an application must be made under Directive 2001/18/EC. If the GMO is to be used in food or feed (but it is not cultivated in the EEA) then a single application for both food and feed purposes under Regulation 1829/2003 should be made. If the GMO is used in feed or food and it is cultivated in the EEA, an application for both cultivation and food/feed purposes needs to be carried out under Regulation (EC) 1829/2003. A different EU regulation, Regulation (EC) 1830/2003, regulates the labeling of products that contain GMOs that are placed on the EEA market. Directive 2001/18/EC was amended by Directive (EU) 2015/412 which gives EEA member states more flexibility to allow, restrict or prohibit cultivating GMOs in their territory, on a range of environmental grounds, even if such crops were previously authorized at EEA level. Under Directive 2015/412, EEA member state restrictions or prohibitions can only cover cultivation, and not the free circulation and import of genetically modified seeds and plant propagation material, and should be in conformity with the internal market rules of the EU Treaties.

Further EU legislation may be applicable to GM foods such as Directive 2009/41/EC on contained use of genetically modified micro-organisms and Regulation (EC) 1946/2003 on transboundary movements of GMOs.

We cannot predict whether or when any governmental authority will change its regulations with respect to any potential food or agricultural products that we develop alone or with collaborators. Advocacy groups have engaged in publicity campaigns and filed lawsuits in various countries against companies and regulatory authorities seeking to halt biotechnology approval activities or influence public opinion against genetically engineered products. In addition, governmental reaction to negative publicity concerning genetically edited agricultural products could result in greater regulation of genetic research and derivative products or regulatory costs that render our or our collaborators' development of potential food or agricultural products cost prohibitive. Our collaborators may use or integrate our products or technology into other products in ways that could subject those collaborators or products to additional regulation.

The overall agricultural industry is susceptible to agricultural price changes, and we may be exposed to risks from changes in commodity prices.

Changes in the prices of agricultural products could result in changes in demand for and prices of food and agricultural products that we or our collaborators may develop. We may be susceptible to these changes as a result of factors beyond our control, such as general economic conditions, seasonal fluctuations, weather conditions, demand, food safety concerns, product recalls and government regulations, subsidies or market export tariffs. If demand for agricultural products that we or our collaborators may develop is negatively impacted, our potential revenues under collaboration agreements for such products may decline, which could adversely affect our results of operations.

The successful commercialization of any food or agricultural products we develop will depend in part on our collaborators' ability to produce high-quality plant, vegetative propagation material and seeds cost-effectively on a large scale and to accurately forecast demand for such potential products, and they may be unable to do so.

The production of commercial-scale quantities of food or agricultural products or seeds for them requires the multiplication of the plants, vegetative propagation material or seeds through a succession of plantings and seed harvests. The cost-effective production of high-quality, high-volume quantities of such products or seeds may depend in part on our collaborators' abilities to scale production processes to produce plants and seeds in sufficient quantity to meet demand. Our collaborators' existing or future plant and seed production techniques may not enable timely meeting of large-scale production goals cost-effectively for any potential food or agricultural products that we and our collaborators may develop. Although we have worked with some of the largest plant biotechnology companies to edit gene targets and develop potential product candidates in a variety of crop plants, no commercial food or agricultural products have ever been developed using our technology.

In addition, because of the length of time it takes to produce commercial quantities of marketable plants and seeds, our collaborators will need to make seed production decisions well in advance of food product sales. The ability to accurately forecast demand can be adversely affected by a number of factors outside of their control, including changes in market conditions, environmental factors, such as pests and diseases, and adverse weather conditions.

The commercial success of any consumer-centric food or agricultural products that we or our collaborators may develop is reliant on the needs of food manufacturers and the recognition of shifting consumer preferences.

The commercial success of any consumer-centric products depends in part on the ability of the food manufacturer to accurately determine the shifting needs and desires of the ultimate consumer. We will not control the marketing, distribution labeling or any other aspects of the sale and commercialization of the manufacturers' food products. Consumer preferences may be a significant driver in the success of food manufacturers in their efforts to sell food and agricultural products, including products that we or our collaborators may develop. While current trends indicate that consumer preferences may be moving towards "healthier" options, we cannot predict whether such trends will continue or which types of food products will be demanded by consumers in the future. Additionally, as health and nutritional science continues to progress, consumer perception of what foods, nutrients and ingredients are considered "healthy" may shift. We and our collaborators may not be dynamic enough in responding to consumer trends and creating products that will be demanded by consumers in the future. In addition, if consumer demand is lower than our estimates or those of our collaborators, our ability to realize revenues from potential food or agricultural products may be limited. Failure by our collaborators to successfully recognize consumer trends could lower demand for potential food or agricultural products that we or our collaborators may develop, which could harm our business, results of operations and financial condition.

Some of the potential food products we develop alone or with collaborators may be distributed into markets or countries in which they have not received regulatory approval, which may result regulatory challenges or lawsuits.

The scale of the agricultural industry may make it difficult to monitor and control the distribution of any potential food products that we develop alone or with collaborators. As a result, such products may be sold inadvertently within jurisdictions where they are not approved for distribution. Such sales may lead to regulatory challenges or lawsuits against us, which could result in significant expenses and divert our management's attention, which could harm our business, results of operations and financial condition.

Risks Related to Our Organization, Structure and Operations

The ongoing novel coronavirus disease, COVID-19 has impacted our business, and any other pandemic, epidemic or outbreak of an infectious disease may materially and adversely impact our business, including our preclinical studies and clinical trials.

In March 2020, the World Health Organization designated the outbreak of the novel strain of coronavirus known as COVID-19 as a global pandemic, and COVID-19 has spread to multiple global regions, including the United States and Europe. The ongoing pandemic and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. In response to the spread of COVID-19 and in accordance with local guidelines, we have implemented measures to mitigate exposure risks and support operations. The health and safety program we have initiated requiring mandatory use of face masks, social distancing, sanitary handwashing practices, use of personal protective equipment stations, stringent cleaning and sanitization of all facilities and measures to reduce total occupancy in facilities, as well as temperature and symptom screening procedures at each location may not sufficiently protect our employees. We have communicated to our employees that based on their comfort level, regardless of role, they may elect not to come to work. Any resurgence of outbreaks or new regulatory orders or guidance or self-imposed protective measures we impose could require reversal of our previously eased restrictions to our on-site activities and, as a result, adversely impact our business, including our preclinical studies and clinical trials.

As a result of the COVID-19 pandemic or other pandemic, epidemic or outbreak of an infectious disease, we have and may continue to experience disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- interruptions in preclinical studies due to restricted or limited operations at our laboratory facility;
- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; and
- interruption or delays to our sourced discovery and clinical activities.

The COVID-19 pandemic continues to evolve. Disruptions, competing resource demands and safety concerns caused by the COVID-19 pandemic have caused, and may continue to cause, delays in our clinical trial site activation and our ability to enroll patients. We may also experience other difficulties, disruptions or delays in conducting preclinical studies or initiating, enrolling, conducting or completing our planned and ongoing clinical trials, and we may incur other unforeseen costs as a result. The extent to which the outbreak impacts our business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. If we or any of the third parties with whom we engage were to experience shutdowns or any further business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted. Additionally, the magnitude of the economic impact brought by and the duration of the COVID-19 pandemic is difficult to assess or predict and may continue to result in significant disruption of global financial markets, which may reduce our ability to access capital and negatively affect our liquidity.

We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

As of March 31, 2021, we had 237 full-time employees. We will need to significantly expand our organization, and our future financial performance, ability to develop and commercialize product candidates alone or with collaborators and ability to compete effectively will depend in part on our ability to effectively manage any future growth. We may have difficulty identifying, hiring and integrating new personnel. Many of the biotechnology companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer history than we do. If we are unable to continue to attract and retain high-quality personnel and consultants, the rate and success at which we can identify and develop product candidates, enter into collaborative arrangements and otherwise operate our business will be limited.

Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors.

Management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expected expansion of our operations or recruit and train additional qualified personnel. Moreover, the expected physical expansion of our operations may lead to significant costs and may divert our management and business development resources from other projects, such as the development of product candidates. If we are not able to effectively manage the expansion of our operations, it may result in weaknesses in our infrastructure, increase our expenses more than expected, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity. Our future financial performance, ability to successfully commercialize any of our product candidates and our ability to compete effectively will depend, in part, on our ability to effectively manage any future growth.

We may engage in transactions that could disrupt our business, cause dilution to our stockholders or reduce our financial resources.

In the future, we may enter into transactions to acquire or in-license rights to product candidates, products or technologies or to acquire other businesses. If we do identify suitable candidates, we may not be able to enter into such transactions on favorable terms, or at all. Any such acquisitions or in-licenses may not strengthen our competitive position, and these transactions may be viewed negatively by customers or investors. We may decide to incur debt in connection with an acquisition or in-license, which may negatively impact our financial condition and restrict our operations, or issue our common stock or other equity securities to the stockholders of the acquired company, which would reduce the percentage ownership of our existing stockholders. We could incur losses resulting from undiscovered liabilities of the acquired business that are not covered by the indemnification we may obtain from the sellers of the acquired business. In addition, we may not be able to successfully integrate the acquired personnel, technologies and operations into our existing business in an effective, timely and non-disruptive manner. Such transactions may also divert management attention from day-to-day responsibilities, increase our expenses and reduce our cash available for operations and other uses. We cannot predict the number, timing or size of future acquisitions or in-licenses or the effect that they might have on our operating results.

Our future success depends on our key executives, as well as attracting, retaining and motivating qualified personnel.

We are highly dependent on the research and development experience, technical skills, leadership and continued service of certain members of our management and scientific teams. Although we have formal employment agreements with our executive officers, these agreements do not prevent them from terminating their employment with us at any time. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

Recruiting and retaining qualified scientific, clinical, manufacturing and, if we retain commercialization responsibility for any product candidate we develop alone or with collaborators, sales and marketing personnel will also be critical to our success. For instance, we have commenced a transition plan for our Chief Executive Officer and recently appointed a Chief Medical Officer to succeed our departed Chief Medical Officer. We may not be able to attract new or successor personnel on acceptable terms or at all given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategies. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. The inability to recruit, integrate, motivate and retain additional skilled and qualified personnel, or the loss of services of certain executives, key employees, consultants or advisors, may impede the progress of our research, development and commercialization objectives and have a material adverse effect on our business.

We are subject to increased costs as a result of operating as a public company, and our management will be required to devote substantial time to maintaining compliance initiatives and corporate governance practices, including establishing and maintaining proper and effective internal control over financial reporting.

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. We are subject to the Securities Exchange Act of 1934, as amended, or the Exchange Act, including the reporting requirements thereunder, the Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Stock Market LLC ("Nasdaq") and other applicable securities rules and regulations, including requirements related to the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs, making some activities more difficult, time consuming or costly, and increasing demand on our systems and resources.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 ("Section 404") we are required to furnish a report by our management on our internal control over financial reporting. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 of the Sarbanes-Oxley Act within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. We may need to hire more employees in the future or engage outside consultants to comply with these requirements, which will further increase our costs and expenses. If we fail to implement the requirements of Section 404 of the Sarbanes-Oxley Act in the required timeframe, we may be subject to sanctions or investigations by regulatory authorities, including the SEC and Nasdaq. Furthermore, if we are unable to conclude that our internal control over financial reporting is effective, our 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 regulatory authorities. Failure to implement or maintain an effective internal control system could also restrict our future access to the capital markets.

Our business and operations would suffer in the event of system failures or security breaches.

Despite the implementation of security measures, our computer systems, as well as those of third parties with which we have relationships, are vulnerable to damage from computer viruses, unauthorized access, natural and manmade disasters, terrorism, war and telecommunication and electrical failures. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. As a result of the COVID-19 pandemic, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the technologies used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. While we do not believe that we have experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our or their operations, it could result in delays and/or material disruptions of our research and development programs. For example, the loss of trial data from completed, ongoing or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the development of our product candidates could be delayed.

The U.S. federal and various state and foreign governments have enacted or proposed requirements regarding the collection, distribution, use, security and storage of personally identifiable information and other data relating to individuals, and U.S. federal and state consumer protection laws are being applied to enforce regulations related to the online collection, use and dissemination of data. In the ordinary course of our business, we and third parties with which we have relationships will continue to collect and store sensitive data, including intellectual property, clinical trial data, proprietary business information, personal data and personally identifiable information of our clinical trial subjects and employees, in data centers and on networks. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our and our collaborators' security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or internal bad actors, breaches due to employee error, technical vulnerabilities, malfeasance or other disruptions. A number of proposed and enacted federal, state and international laws and regulations obligate companies to notify individuals of security breaches involving particular personally identifiable information, which could result from breaches experienced by us or by third parties, including collaborators, vendors, contractors or other organizations with which we have formed strategic relationships. Although, to our knowledge, neither we nor any such third parties have experienced any material security breach, and even though we may have contractual protections with such third parties, any such breach could compromise our or their networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure, notifications, follow-up actions related to such a security breach or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information and

significant costs, including regulatory penalties, fines and legal expenses, and such an event could disrupt our operations, cause us to incur remediation costs, damage our reputation and cause a loss of confidence in us and our or such third parties' ability to conduct clinical trials, which could adversely affect our reputation and delay our research and development programs.

Our insurance policies are expensive and protect us only from some business risks, which leaves us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. If we obtain marketing approval for any product candidates that we or our collaborators may develop, we intend to acquire insurance coverage to include the sale of commercial products, but we may be unable to obtain such insurance on commercially reasonable terms or in adequate amounts. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination.

Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and clinical trials or regulatory approvals for any of our product candidates could be suspended. We also expect that operating as a public company will make it more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors, our board committees or as our executive officers.

Insurance coverage is becoming increasingly expensive, and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. We do not know if we will be able to maintain existing insurance with adequate levels of coverage, and any liability insurance coverage we acquire in the future may not be sufficient to reimburse us for any expenses or losses we may suffer. A successful liability claim or series of claims brought against us could require us to pay substantial amounts and cause our share price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business, including preventing or limiting the development and commercialization of any product candidates that we or our collaborators may develop.

If we or any of our contract manufacturers or other suppliers fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur significant costs.

We and any of our contract manufacturers and suppliers are subject to numerous federal, state and local environmental, health and safety laws, regulations and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities. We also could incur significant costs associated with civil or criminal fines and penalties.

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research and product development efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies (under which we currently have an aggregate of approximately $10 million in coverage) specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals for any product candidate we develop alone or with collaborators could be suspended, which could have a material adverse effect on our business and financial condition.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws, regulations and permitting requirements, and any third-party contract manufacturers and suppliers we engage will also be subject to such current and future regulations and requirements. These current or future laws, regulations and permitting requirements may impair our research, development or production efforts. Failure to comply with these laws, regulations and permitting requirements, either by us or by any third-party contract manufacturers and suppliers we engage, also may result in substantial fines, penalties or other sanctions or business disruption.

Our business operations, including our current and future relationships with third parties, may expose us to penalties for potential misconduct or improper activity, including non-compliance with regulatory standards and requirements.

Complex laws constrain our business and the financial arrangements and relationships through which we conduct our operations, including how we may research, market, sell and distribute product candidates alone or with collaborators. We are exposed to the risk of fraud or other misconduct by our employees, consultants and collaborators and, if we or our collaborators commence clinical trials and proceed to commercialization, our principal investigators and commercial partners, as well as healthcare professionals, third-party payors, patient organizations and customers. For example, misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in the EU and other jurisdictions, provide accurate information to the FDA, the European Commission and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, false and/or misleading statements, corruption of government officials, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing, promotion, sales commission and customer incentive programs and other business arrangements. Such misconduct also could involve the improper use or misrepresentation of information obtained in the course of clinical trials, creating fraudulent data in preclinical studies or clinical trials, illegal misappropriation of study materials or other property, or improper interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our or our collaborators' reputations.

Ensuring that our internal operations and current and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any 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, additional reporting requirements and oversight if subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, disgorgement, individual 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 similar penalties, such as 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.

We have adopted policies applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent such activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with applicable laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of any of the penalties discussed above and have a significant impact on our business and financial condition.

We are subject to complex tax rules relating to our business, and any audits, investigations or tax proceedings could have a material adverse effect on our business, results of operations and financial condition.

We are subject to income and non-income taxes in the United States. Income tax accounting often involves complex issues, and judgment is required in determining our provision for income taxes and other tax liabilities. In May 2018 we formed a subsidiary in Australia, in June 2019 we formed a subsidiary in the United Kingdom, and we may operate in other non-US jurisdictions in the future. We could become subject to income and non-income taxes in non-US jurisdictions as well. In addition, many jurisdictions have detailed transfer pricing rules, which require that all transactions with non-resident related parties be priced using arm's length pricing principles within the meaning of such rules. The application of withholding tax, goods and services tax, sales taxes and other non-income taxes is not always clear and we may be subject to tax audits relating to such withholding or non-income taxes. We believe that our tax positions are reasonable and our tax reserves are adequate to cover any potential liability. We are currently not subject to any tax audits. However, the Internal Revenue Service or other taxing authorities may disagree with our positions. If the Internal Revenue Service or any other tax authorities were successful in challenging our positions, we may be liable for additional tax and penalties and interest related thereto or other taxes, as applicable, in excess of any reserves established therefor, which may have a significant impact on our results and operations and future cash flow.

We may not be able to utilize all, or any, of our net operating loss carryforwards.

We have incurred substantial losses during our history, do not expect to become profitable in the near future, and we may never achieve profitability. As of December 31, 2020, we had U.S. federal, state, and foreign net operating loss carryforwards of $172.7 million, $116.5 million, and $0.6 million, respectively. Our federal net operating loss carryforwards of $19.7 million will begin to expire in 2030 while the remaining federal net operating loss carryforwards of $153.0 million carry forward indefinitely. The state net operating loss carryforwards begin to expire in 2025. In addition, as of December 31, 2020, we have U.S. federal and state research and development tax credits of $9.9 million and an amount less than $0.1 million available to offset future U.S. federal and state income taxes, which begin to expire in 2027 and 2030, respectively. At December 31, 2020 and December 31, 2019, we had federal Orphan Drug credits of $6.0 million and $1.8 million, respectively, which begin to expire in 2038.

Changes in tax laws or regulations may adversely impact our ability to utilize all, or any, of our net operating loss carryforwards. For example, legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act, significantly revised the Internal Revenue Code of 1986, as amended. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Cuts and Jobs Act may affect us, and certain aspects of the Tax Cuts and Jobs Act could be repealed or modified in future legislation. For example, the CARES Act modified certain provisions of the Tax Cuts and Jobs Act. Under the CARES Act, net operating losses arising in a tax year beginning after December 31, 2017, and before January 1, 2021, generally may now be carried back five years. Under the Tax Cuts and Jobs Act, as modified by the CARES Act, unused losses generated in taxable years ending after December 31, 2017 will not expire and may be carried forward indefinitely, but the deductibility of such net operating losses 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 to the Tax Cuts and Jobs Act or the CARES Act.

As of March 31, 2021, we have a valuation allowance for the full amount of our net deferred tax assets as the realization of the net deferred tax assets is not determined to be more likely than not. In addition, Sections 382 and 383 of the Code limit a corporation's ability to utilize its net operating loss carryforwards and certain other tax attributes (including research credits) to offset any future taxable income or tax if the corporation experiences a cumulative ownership change of more than 50% over any rolling three-year period. State net operating loss carryforwards (and certain other tax attributes) may be similarly limited. A Section 382 ownership change can therefore result in significantly greater tax liabilities than a corporation would incur in the absence of such a change, and any increased liabilities could adversely affect the corporation's business, results of operations, financial condition and cash flow. We have not yet determined if any prior change in the ownership of our equity or any change in such ownership in connection with our IPO, would trigger a Section 382 ownership change. It is possible that such a Section 382 ownership change has already occurred in prior periods. Furthermore, additional ownership changes may occur in the future as a result of events over which we will have little or no control, including purchases and sales of our equity by our 5% stockholders, the emergence of new 5% stockholders, additional equity offerings or redemptions of our stock or certain changes in the ownership of any of our 5% stockholders. As a result, our pre-2018 net operating loss carryforwards (and research tax credits) may expire prior to being used, and our net operating loss carryforwards and tax credits generated in 2018 and thereafter will be subject to a percentage limitation, upon an ownership change. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. As a result, even if we attain profitability, we may be unable to use all or a material portion of our NOLs and other tax attributes, which could adversely affect our future cash flows.

Risks Related to Our Reliance on Third Parties

We have entered into significant arrangements with collaborators and expect to depend on collaborations with third parties for certain research, development and commercialization activities, and if any such collaborations are not successful, it may harm our business and prospects.

We have sought in the past, and anticipate that we will continue to seek in the future, third-party collaborators for the research, development and commercialization of certain product candidates and the research and development of certain technologies. For example, we are party to the Development and License Agreement with Lilly. Under this agreement, we are focused on research and development of *in vivo* gene editing products that utilize or incorporate our ARCUS nucleases. In addition, our food platform is based on a consumer-centric model, whereby our research and development activities and potential revenues are based on the needs and commercial success of our collaborators. Our likely collaborators for other product research and development arrangements include large and mid-size pharmaceutical and biotechnology companies biotechnology and food, beverage, nutrition and agricultural biotechnology companies, and our likely collaborators for other technology research and development arrangements include universities and other research institutions.

Working with collaborators poses several significant risks. We have limited control over the amount and timing of resources that our collaborators dedicate to the product candidates or technologies we may seek to develop with them. A variety of factors may impact resource allocation decisions of collaborators, such as study or trial results, changes in the collaborator's strategic focus, turnover in personnel responsible for the development activities, financial capacity or external factors such as a business combination or change in control that diverts resources or creates competing priorities. Collaboration agreements may not lead to development or

commercialization of product candidates or the development of technologies in the most efficient manner or at all. Resource allocation and other developmental decisions made by our collaborators may result in the delay or termination of research programs, studies or trials, repetition of or initiation of new studies or trials or provision of insufficient funding or resources for the completion of studies or trials or the successful marketing and distribution of any product candidates that may receive approval. Collaborators could independently develop, or develop with third parties, product candidates or technologies that compete directly or indirectly with our product candidates or technologies if the collaborators believe that competitive products or technologies are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours. Collaborators may not properly obtain, maintain, enforce or defend our intellectual property or proprietary rights or may use our proprietary information in such a way that could jeopardize or invalidate our proprietary information or expose us to potential litigation. Disputes may arise between us and our collaborators that result in the delay or termination of the research, development or commercialization activities or that result in costly litigation or arbitration that diverts management attention and resources.

Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. If our collaborations do not result in the successful development and commercialization of product candidates or technologies, or if one of our collaborators terminates its agreement with us, we may not receive any future funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of product candidates or technologies could be delayed, and we may need additional resources to develop such product candidates or technologies. For example, we waived earned, but unpaid milestone payments in connection with the termination of the Servier Agreement. Further, as a result of the termination of the Gilead Agreement, we are no longer entitled to receive certain milestone payments, our submission of an IND for our *in vivo* chronic HBV program has been delayed and we are currently exploring alternative opportunities to enable to continued development of ARCUS-based HBV therapies. In connection with this termination, and if any of our other collaborators terminates its agreement with us, we may be unable to find a suitable replacement collaborator or any replacement collaborator or attract new collaborators and may need to raise additional capital to pursue further development or commercialization of the applicable product candidates or technologies. These events could delay development programs, negatively impact the perception of our company in business and financial communities or cause us to have to cease development of the product candidate covered by the collaboration arrangement. Failure to develop or maintain relationships with any current collaborators could result in the loss of opportunity to work with that collaborator or reputational damage that could impact our relationships with other collaborators in the relatively small industry communities in which we operate. Moreover, all of the risks relating to product development, regulatory approval and commercialization described in this Quarterly Report on Form 10-Q apply to the activities of our collaborators. If our existing collaboration agreements or any collaborative or strategic relationships we may establish in the future are not effective and successful, it may damage our reputation and business prospects, delay or prevent the development and commercialization of product candidates and inhibit or preclude our ability to realize any revenues.

If we are not able to establish collaborations on commercially reasonable terms, we may have to alter our research, development and commercialization plans.

Our research and product development programs and the potential commercialization of any product candidates we develop alone or with collaborators will require substantial additional cash to fund expenses, and we expect that we will continue to seek collaborative arrangements with others in connection with the development and potential commercialization of current and future product candidates or the development of ancillary technologies. We face significant competition in establishing relationships with appropriate collaborators. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Whether we 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 a number of factors. Those factors may include, among other things and as applicable for the type of potential product or technology, an assessment of the opportunities and risks of our technology, the design or results of studies or trials, the likelihood of approval, if necessary, by the USDA, the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products and technologies and industry and market conditions generally.

Current or future collaborators may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us. Additionally, we may be restricted under existing collaboration agreements from entering into future agreements on certain terms or for certain development activities with potential collaborators. For example, we have granted exclusive rights or options to Servier for certain targets, and during the terms of our respective collaboration agreements with them we will be restricted from granting rights to other parties to use our ARCUS technology to pursue potential products that address those targets. Similarly, our collaboration agreements have in the past and may in the future contain non-competition provisions that could limit our ability to enter into strategic collaborations with future collaborators.

Collaborations are complex and time-consuming to negotiate and document. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we do enter into additional collaboration agreements, the negotiated terms may force us

to relinquish rights that diminish our potential profitability from development and commercialization of the subject product candidates or others. If we are unable to enter into additional collaboration agreements, we may have to curtail the research and development of the product candidate or technology for which we are seeking to collaborate, reduce or delay research and development programs, delay potential commercialization timelines, reduce the scope of any sales or marketing activities or undertake research, development or commercialization activities at our own expense. If we elect to increase our expenditures to fund research, 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.

We expect to rely on third parties to conduct, supervise and monitor our clinical trials and some aspects of our research and preclinical testing, and if those third parties do not successfully carry out their contractual duties, comply with regulatory requirements, or otherwise perform in a satisfactory manner, we may not be able to obtain regulatory approval or commercialize product candidates, or such approval or commercialization may be delayed, and our business may be substantially harmed.

We may rely on medical institutions, universities, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct preclinical studies and future clinical trials for our product candidates. Nevertheless, we will be responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on such third parties will not relieve us of our regulatory responsibilities.

Although we intend to design the trials for our product candidates either alone or with collaborators, third parties may conduct all of the trials. As a result, many important aspects of our research and development programs, including their conduct and timing, will be outside of our direct control. Our reliance on third parties to conduct future studies and trials will also result in less direct control over the management of data developed through studies and trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes and difficulties in coordinating activities. Outside parties may have staffing difficulties, fail to comply with contractual obligations, experience regulatory compliance issues, undergo changes in priorities, become financially distressed or form relationships with other entities, some of which may be our competitors. We also face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs or other third parties, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. For any violations of laws and regulations during the conduct of our preclinical studies and future clinical trials, we could be subject to warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with regulations, commonly referred to as Good Clinical Practices (“GCPs”) for conducting, monitoring, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. If we, our collaborators, our CROs or other third parties fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We also are required to register certain ongoing clinical trials and post the results of such completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

If our CROs or other third parties do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, trials for product candidates may be extended, delayed or terminated, and we or our collaborators may not be able to obtain regulatory approval for, or successfully commercialize, any product candidate that we develop. If we are required to repeat, extend the duration of or increase the size of any trials we conduct, it could significantly delay commercialization and require significantly greater expenditures. As a result of any of these factors, our financial results and the commercial prospects for any product candidate that we or our collaborators may develop would be harmed, our costs could increase and our ability to generate revenues could be delayed.

We expect to rely on third parties to supply raw materials or manufacture product supplies that are necessary for the conduct of preclinical studies, clinical trials and manufacturing of our product candidates, and failure by third parties to provide us with sufficient quantities of products, or to do so at acceptable quality levels or prices and on a timely basis, could harm our business.

We are dependent on third parties for the supply of various biological materials, such as cells, cytokines and antibodies, and the manufacture of product supplies, such as media, plasmids, mRNA and AAV viral vectors, that are necessary to produce our product candidates. The supply of these materials could be reduced or interrupted at any time. In such case, identifying and engaging an alternative supplier or manufacturer could result in delay, and we may not be able to find other acceptable suppliers or manufacturers on acceptable terms, or at all. Switching suppliers or manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines. If we change suppliers or manufacturers for commercial production, applicable regulatory agencies may require us to conduct additional studies or trials. If key suppliers or manufacturers are lost, or if the supply of

the materials is diminished or discontinued, we or our collaborators may not be able to develop, manufacture and market product candidates in a timely and competitive manner, or at all. If any of our product candidates receives approval, we will likely need to seek alternative sources of supply of raw materials or manufactured product supplies and there can be no assurance that we will be able to establish such relationships to provide such supplies on commercially reasonable terms or at acceptable quality levels, if at all. If we are unable to identify and procure additional sources of supply that fit our required needs, we could face substantial delays or incur additional costs in procuring such materials. In addition, manufactured product supplies are subject to stringent manufacturing processes and rigorous testing. Delays in the completion and validation of facilities and manufacturing processes of these materials could adversely affect the ability to complete studies or trials and commercialize any product candidates that may receive approval. Furthermore, if our suppliers or manufacturers encounter challenges relating to employee turnover, the supply and manufacturing of our materials could be delayed or adversely affected as such parties seek to hire and train new employees. These factors could cause the delay of studies or trials, regulatory submissions, required approvals or commercialization of product candidates that we or our collaborators may develop, cause us to incur higher costs and prevent us from commercializing products successfully. Furthermore, if our suppliers or manufacturers fail to meet contractual requirements, and we are unable to secure one or more replacements capable of production at a substantially equivalent cost, our or our collaborators' studies or trials may be delayed and we could lose potential revenue.

We may rely on third parties for at least a portion of the manufacturing process of product candidates, and failure by those parties to adequately perform their obligations could harm our business.

While we expect to use our MCAT facility for certain of our clinical-scale manufacturing and processing needs, we may continue to rely on outside vendors for at least a portion of the manufacturing process of product candidates that we or our collaborators may develop. The facilities used by our contract manufacturers to manufacture product candidates must be approved by the FDA or other foreign regulatory agencies pursuant to inspections that will be conducted after we submit an application to the FDA or other foreign regulatory agencies. To the extent that we or our collaborators engage third parties for manufacturing services, we will not control the manufacturing process of, and will be completely dependent on, our contract manufacturing providers for compliance with cGMP requirements for manufacture of the product candidates. We have not yet caused any product candidates to be manufactured or processed on a commercial scale and may not be able to do so. We will make changes as we work to optimize the manufacturing process, and we cannot be sure that even minor changes in the process will result in products that are safe and effective. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of 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 any of our or our collaborators' potential products.

Risks Related to Intellectual Property

Our ability to compete may decline if we do not adequately protect our proprietary rights, and if our proprietary rights do not provide a competitive advantage.

Our commercial success depends upon obtaining and maintaining proprietary rights to our intellectual property estate, including rights relating to ARCUS and to our product candidates, as well as successfully defending these rights against third-party challenges and successfully enforcing these rights to prevent third-party infringement. We will only be able to protect ARCUS and product candidates from unauthorized use by third parties to the extent that valid and enforceable patents cover them. Our ability to obtain and maintain patent protection for ARCUS and our product candidates is uncertain due to a number of factors, including that:

- we may not have been the first to invent the technology covered by our pending patent applications or issued patents;
- we may not be the first to file patent applications covering product candidates, including their compositions or methods of use, as patent applications in the United States and most other countries are confidential for a period of time after filing;
- our compositions and methods may not be patentable;
- our disclosures in patent applications may not be sufficient to meet the statutory requirements for patentability;
- any or all of our pending patent applications may not result in issued patents;
- others may independently develop identical, similar or alternative technologies, products or compositions or methods of use thereof;
- others may design around our patent claims to produce competitive technologies or products that fall outside of the scope of our patents;

- we may fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection;
- we may not seek or obtain patent protection in countries that may eventually provide us a significant business opportunity;
- any patents issued to us may not provide a basis for commercially viable products, may not provide any competitive advantages or may be successfully challenged by third parties;
- others may identify prior art or other bases upon which to challenge and ultimately invalidate our patents or otherwise render them unenforceable; and
- the growing scientific and patent literature relating to engineered endonucleases, including our own patents and publications, may make it increasingly difficult or impossible to patent new engineered nucleases in the future.

Even if we have or obtain patents covering ARCUS or any product candidates or compositions, we and our collaborators may still be barred from making, using and selling such product candidates or technologies because of the patent rights of others. Others may have filed, and in the future may file, patent applications covering compositions, products or methods that are similar or identical to ours, which could materially affect our ability to successfully develop any product candidates or to successfully commercialize any approved products alone or with collaborators. In addition, because patent applications can take many years to issue, there may be currently pending applications unknown to us that may later result in issued patents that we or our collaborators may infringe. These patent applications may have priority over patent applications filed by us.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. For example, in August 2019, the PTAB, of the United States Patent and Trademark Office (“the USPTO”) initiated two patent interferences, administrative proceedings within the USPTO, involving a family of patents that have been issued to us and a pending patent application filed by a third party. An interference is conducted by the PTAB when opposing parties have applied for patent claims to the same invention or substantially the same invention. The interference is conducted to determine which party, if either, is entitled to claims to the subject matter of the interference. In October 2020, we announced the PTAB has issued judgements in our favor in two patent interference proceedings that challenged nine U.S. patents we owned. The patents, which issued in 2018, relate to allogeneic CAR T cells produced by inserting a gene encoding a CAR into the TRAC locus, as well as methods of using those cells for cancer immunotherapy. In the interference proceedings, a third party argued that it had invented the technology in 2012. The PTAB, however, found that the third-party patent application did not satisfy the written description requirement and rejected these claims while maintaining the claims in all nine of our patents. Any adverse outcome in future interference proceedings could affect our competitive position, including, without limitation, loss of some or all of our involved patent claims, limiting our ability to stop others from using or commercializing similar or identical technology and products, which could harm our business, financial condition and results of operations. Protecting our patent rights in connection with such proceeding may also be expensive and may involve the diversion of significant management time.

Furthermore, we cannot guarantee that any patents will be issued from any pending or future owned or licensed patent applications. Thus, even if our patent applications issue as patents, they may not issue in a form that will provide us with meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. In addition, third parties may be able to develop products that are similar to, or better than, ours in a way that is not covered by the claims of our patents, or may have blocking patents that could prevent us from marketing our products or practicing our own patented technology. Moreover, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however the life of a patent, and the protection it affords, is limited. Without patent protection for current or future product candidates, we may be open to competition from generic versions of such potential products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to those we or our collaborators may develop.

Obtaining and maintaining a patent portfolio entails significant expense, including periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and patent applications. These expenditures can be at numerous stages of prosecuting patent applications and over the lifetime of maintaining and enforcing issued patents. We may or may not choose to pursue or maintain protection for particular intellectual property in our portfolio. If we choose to forgo patent protection or to allow a patent application or patent to lapse purposefully or inadvertently, our competitive position could suffer. There are situations, however, in which failure to make certain payments or noncompliance with certain requirements in the patent process can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Legal action that may be required to enforce our patent rights can be expensive and may involve the diversion of significant management time. There can be no assurance that we will have sufficient financial or other resources to file and pursue infringement claims, which typically last for years before they are concluded. In addition, these legal actions could be unsuccessful and result in the invalidation of our patents, a finding that they are unenforceable or a requirement that we enter into a licensing agreement with or pay monies to a third party for use of technology covered by our patents. We may or may not choose to pursue litigation or other actions against those that have infringed on our patents, or have used them without authorization, due to the associated expense and time commitment of monitoring these activities. If we fail to successfully protect or enforce our intellectual property rights, our competitive position could suffer, which could harm our results of operations.

Many biotechnology companies and academic institutions are currently pursuing a variety of different nuclease systems for genome editing technologies using zinc finger nucleases, TALENs, and CRISPR/Cas9 and the use of those nucleases in cancer immunotherapy, gene therapy and genome editing. Although those nucleases are physically and chemically different from our ARCUS nucleases, those companies and institutions may seek patents that broadly cover aspects of cancer immunotherapy, gene therapy and genome editing using nucleases generally. Such patents, if issued, valid and enforceable, could prevent us from marketing our product candidates, if approved, practicing our own patented technology, or might require us to take a license which might not be available on commercially reasonable terms or at all. While we expect that we will continue to be able to patent our ARCUS nucleases for the foreseeable future, as the scientific and patent literature relating to engineered endonucleases increases, including our own patents and publications, it may become more difficult or impossible to patent new engineered endonucleases in the future.

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

We are a party to a number of intellectual property license agreements that are important to our business and expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us. We may need to outsource and rely on third parties for many aspects of the development, sales and marketing of any products covered under our current and future license agreements. Delay or failure by these third parties could adversely affect the continuation of our license agreements with our licensors. If we fail to comply with any of our obligations under these agreements, or we are subject to a bankruptcy, our licensors may have the right to terminate the license, in which event we would not be able to market any products covered by the license.

In addition, disputes may arise regarding the payment of the royalties due to licensors in connection with our exploitation of the rights we license from them. Licensors may contest the basis of royalties we retained and claim that we are obligated to make payments under a broader basis. In addition to the costs of any litigation we may face as a result, any legal action against us could increase our payment obligations under the respective agreement and require us to pay interest and potentially damages to such licensors.

In some cases, patent prosecution of our licensed technology is controlled solely by the licensor. If such licensor fails to obtain and maintain patent or other protection for the proprietary intellectual property we license from such licensor, we could lose our rights to such intellectual property or the exclusivity of such rights, and our competitors could market competing products using such intellectual property. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we or our collaborators may be unable to develop or commercialize the affected product candidates, which could harm our business significantly. In other cases, we control the prosecution of patents resulting from licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our licensing partners.

For example, our license agreement with Duke, which we refer to as the Duke License, imposes various payment, royalty and other obligations on us in order to maintain the license. If we fail to make royalty payments or milestone payments required under the Duke License, Duke may terminate the agreement. If we or our affiliates obtain a license from a third party to practice the Duke technology, we must use commercially reasonable efforts to secure a covenant not to sue Duke, or any of its faculty, students, employees or agents, for any research and development efforts conducted at Duke that resulted in the creation of any of its inventions or intellectual property rights arising therefrom. Additionally, because development of the Duke technology was funded in part by the U.S. government, it is subject to certain government rights and obligations, including the requirement that any products sold in the United States based upon such technology be substantially manufactured in the United States.

In addition, our cross-license agreement with Cellectis, or the Cellectis License, imposes various obligations on us in order to maintain the license. In particular, if we participate in or provide assistance to a third party challenging the validity, enforceability and/or patentability of any claim of any patent licensed to us by Cellectis under this agreement, Cellectis may terminate the agreement. The Cellectis License does not provide exclusive rights to use the licensed intellectual property and technology or rights in all relevant fields in which we may wish to develop or commercialize our technology and products in the future. As a result, we are not able to prevent competitors from developing and commercializing competitive products and technology that may use this technology. Additionally, we do not have the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents

and patent applications covering the technology that we license from Cellectis. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained and defended in a manner consistent with the best interests of our business. If Cellectis or other licensors fail to prosecute, maintain, enforce and defend the patents subject to such licenses, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our products that are the subject of such licensed rights could be adversely affected.

If we fail to comply with our obligations under the Duke License or the Cellectis License, or arrangements with any other licensors, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any product candidate that is covered by these agreements, which could materially adversely affect the value of any such product candidate. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

Disputes may arise regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the amounts of royalties, milestones or other payments due to our licensors;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the license agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our collaborators; and
- the priority of invention of patented technology.

Such disputes may be costly to resolve and may divert management's attention away from day-to-day activities. If disputes over intellectual property that we have licensed from third parties prevent or impair our ability to maintain our licensing arrangements on acceptable terms, we or our collaborators may be unable to successfully develop and commercialize the affected product candidates.

Some of our in-licensed intellectual property has been discovered through government funded research and thus may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies, and compliance with such regulations may limit our exclusive rights and our ability to contract with non-U.S. manufacturers.

Certain intellectual property rights that have been in-licensed pursuant to the Duke License have been generated through the use of U.S. government funding and are therefore subject to certain federal regulations. As a result, the U.S. government may have certain rights to intellectual property embodied in our current or future product candidates pursuant to the Bayh-Dole Act of 1980, or the Patent and Trademark Law Amendment. These U.S. government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require the licensor to grant exclusive, partially exclusive or non-exclusive licenses to any of these inventions to a third party if it determines that (1) adequate steps have not been taken to commercialize the invention, (2) government action is necessary to meet public health or safety needs or (3) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). The U.S. government also has the right to take title to these inventions if the licensor fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States, and the Duke License requires that we comply with this requirement. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture the products substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. industry may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. To the extent any of our owned or licensed future intellectual property is also generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply.

If we do not obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation with respect to our product candidates, thereby potentially extending the term of marketing exclusivity for such product candidates, our business may be harmed.

In the United States, a patent that covers an FDA-approved drug or biologic may be eligible for a term extension designed to restore the period of the patent term that is lost during the premarket regulatory review process conducted by the FDA. Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, which permits a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. In the European Union, our product candidates may be eligible for term extensions based on similar legislation. In either jurisdiction, however, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Even if we are granted such extension, the duration of such extension may be less than our request. If we are unable to obtain a patent term extension, or if the term of any such extension is less than our request, the period during which we can enforce our patent rights for that product will be in effect shortened and our competitors may obtain approval to market competing products sooner. The resulting reduction of years of revenue from applicable products could be substantial.

Patents and patent applications involve highly complex legal and factual questions, which, if determined adversely to us, could negatively impact our patent position.

The patent positions of biopharmaceutical and biotechnology companies and other actors in our fields of business can be highly uncertain and typically involve complex scientific, legal and factual analyses. In particular, the interpretation and breadth of claims allowed in some patents covering biopharmaceutical compositions may be uncertain and difficult to determine, and are often affected materially by the facts and circumstances that pertain to the patented compositions and the related patent claims. The standards of the USPTO and its foreign counterparts are sometimes uncertain and could change in the future. Consequently, the issuance and scope of patents cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. U.S. patents and patent applications may also be subject to interference or derivation proceedings, and U.S. patents may be subject to reexamination proceedings, post-grant review and/or *inter partes* review in the USPTO. International patents may also be subject to opposition or comparable proceedings in the corresponding international patent office, which could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such interference, derivation, reexamination, post-grant review, *inter partes* review and opposition proceedings may be costly. Accordingly, rights under any issued patents may not provide us with sufficient protection against competitive products or processes.

Furthermore, even if not challenged, our patents and patent applications may not adequately protect our technology and any product candidates or products that we develop alone or with collaborators or prevent others from designing their products to avoid being covered by our claims. If the breadth or strength of protection provided by the patent applications we hold with respect to product candidates or potential products is threatened, it could dissuade companies from collaborating with us to develop, and could threaten our or their ability to successfully commercialize, such product candidates. Furthermore, for U.S. applications in which any claim is entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third party or instituted by the USPTO in order to determine who was the first to invent any of the subject matter covered by such patent claims.

In addition, changes in, or different interpretations of, patent laws in the United States and other countries may permit others to use our discoveries or to develop and commercialize our technology and product candidates or products without providing any compensation to us, or may limit the scope of patent protection that we are able to obtain. The laws of some countries do not protect intellectual property rights to the same extent as U.S. laws, and those countries may lack adequate rules and procedures for defending our intellectual property rights.

If the patent applications we hold or have in-licensed with respect to our current and future research and development programs and product candidates fail to issue, if their validity, breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our technology or any products and product candidates that we or our collaborators may develop, it could dissuade companies from collaborating with us to develop product candidates, encourage competitors to develop competing products or technologies and threaten our or our collaborators' ability to commercialize future product candidates. Any such outcome could have a material adverse effect on our business.

Third parties may assert claims against us alleging infringement of their patents and proprietary rights, or we may need to become involved in lawsuits to defend or enforce our patents, either of which could result in substantial costs or loss of productivity, delay or prevent the development and commercialization of product candidates, prohibit our use of proprietary technology or sale of potential products or put our patents and other proprietary rights at risk.

Our commercial success depends in part upon our ability to develop, manufacture, market and sell product candidates without alleged or actual infringement, misappropriation or other violation of the patents and proprietary rights of third parties. Litigation relating to infringement or misappropriation of patent and other intellectual property rights in the pharmaceutical, biotechnology and agricultural biotechnology industries is common, including patent infringement lawsuits, interferences, oppositions and reexamination proceedings before the USPTO and corresponding international patent offices. The various markets in which we plan to operate are subject to frequent and extensive litigation regarding patents and other intellectual property rights. In addition, many companies in intellectual property-dependent industries, including the biotechnology, agricultural biotechnology and pharmaceutical industries, have employed intellectual property litigation as a means to gain an advantage over their competitors. Numerous United States, EU and other internationally issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates, and as the biotechnology, agricultural biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the intellectual property rights of third parties. For example, we are aware of certain patents held by third parties relating to the modification of T cells, including the production of CAR T cells. Although conducting clinical trials and other development activities with respect to our CAR T product candidates is not considered an act of infringement in the United States, if and when any of our CAR T product candidates may be approved by the FDA, those third parties may seek to enforce their patents by filing a patent infringement lawsuit against us. As a result of any patent infringement claims, or in order to avoid any potential infringement claims, we may choose to seek, or be required to seek, a license from the third party, which may require payment of substantial royalties or fees, or require us to grant a cross-license under our intellectual property rights, similar to the cross license we granted Cellectis as part of our patent litigation settlement. These licenses may not be available on reasonable terms or at all. Even if a license can be obtained on reasonable terms, the rights may be nonexclusive, which would give our competitors access to the same intellectual property rights. If we are unable to enter into a license on acceptable terms, we or our collaborators could be prevented from commercializing one or more product candidates, or forced to modify such product candidates, or to cease some aspect of our business operations, which could harm our business significantly. We or our collaborators might also be forced to redesign or modify our technology or product candidates so that we no longer infringe the third-party intellectual property rights, which may result in significant cost or delay to us, or which redesign or modification could be impossible or technically infeasible. Even if we were ultimately to prevail, any of these events could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

Further, if a patent infringement suit is brought against us, our collaborators or our third-party service providers, our development, manufacturing or sales activities relating to the product or product candidate that is the subject of the suit may be delayed or terminated. In addition, defending such claims has in the past and may in the future cause us to incur substantial expenses and, if successful, could cause us to pay substantial damages if we are found to be infringing a third party's patent rights. These damages potentially include increased damages and attorneys' fees if we are found to have infringed such rights willfully. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us. In addition, if the breadth or strength of protection provided by the patents and patent applications we own or in-license is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

We have been and may in the future be subject to third-party claims and similar adversarial proceedings or litigation in other jurisdictions regarding our infringement of the patent rights of third parties. Even if such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, and the holders of any such patents may be able to block our or our collaborators' ability to further develop or commercialize the applicable product candidate unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our technologies, compositions, formulations, or methods of treatment, prevention or use, the holders of any such patents may be able to prohibit our use of those technologies, compositions, formulations, methods of treatment, prevention or use or other technologies, effectively blocking our or our collaborators' ability to develop and commercialize the applicable product candidate until such patent expires or is finally determined to be invalid or unenforceable or unless we or our collaborators obtain a license.

Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity, adversely impact prospective customers, cause product shipment delays or prohibit us from manufacturing, marketing or otherwise commercializing our products, services and technology. Any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operation, financial condition or cash flows.

If we or one of our licensors were to initiate legal proceedings against a third party to enforce a patent covering our technology or a product candidate, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the United States and Europe, defendant counterclaims alleging invalidity or unenforceability are common. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Third parties might allege unenforceability of our patents because during prosecution of the patent an individual connected with such prosecution withheld relevant information, or made a misleading statement. The outcome of proceedings involving assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity of patents, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution, but that an adverse third party may identify and submit in support of such assertions of invalidity. 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 on our technology or product candidates. Our patents and other intellectual property rights also will not protect our technology if competitors design around our protected technology without infringing our patents or other intellectual property rights. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, 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. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors view these announcements in a negative light, the price of our common stock could be adversely affected. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings.

Developments in patent law could have a negative impact on our business.

From time to time, the United States Supreme Court (“the Supreme Court”), other federal courts, the United States Congress, or Congress, the USPTO and similar international authorities may change the standards of patentability, and any such changes could have a negative impact on our business. For example, the America Invents Act (“the AIA”), which was passed in September 2011, resulted in significant changes to the U.S. patent system. An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned from a “first-to-invent” to a “first-to-file” system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. Under a “first-to-file” system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. A third party that files a patent application in the USPTO after that date but before us could therefore be awarded a patent covering an invention of ours even if we made the invention before it was made by the third party. Circumstances could prevent us from promptly filing patent applications on our inventions.

The AIA limited where a patentee may file a patent infringement suit and provided opportunities for third parties to challenge any issued patent in the USPTO. Those provisions apply to all of our U.S. patents, regardless of when issued. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. These provisions could increase the uncertainties and costs surrounding the prosecution of our or our licensors’ patent applications and the enforcement or defense of our or our licensors’ issued patents.

Additionally, the Supreme Court has ruled on several patent cases in recent years either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations, and there are other open questions under patent law that courts have yet to decisively address. 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 our patents and patent applications. Depending on decisions by Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways and could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. In addition, the European patent system is relatively stringent in the type of amendments that are allowed during prosecution, but the complexity and uncertainty of European patent laws has also increased in recent years. Complying with these laws and regulations could limit our ability to obtain new patents in the future that may be important for our business.

If we were unable to protect the confidentiality of our trade secrets and enforce our intellectual property assignment agreements, our business and competitive position would be harmed.

In addition to patent protection, because we operate in the highly technical field of development of product candidates and products using genome editing, we rely significantly on trade secret protection in order to protect our proprietary technology and processes. Trade secrets are difficult to protect. Our policy is to enter into confidentiality and intellectual property assignment agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party's relationship with us. These agreements also generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, 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. Our assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. In addition, these agreements may be held unenforceable and may not effectively assign intellectual property rights to us. If our trade secrets and other unpatented or unregistered proprietary information are disclosed, we are likely to lose such trade secret protection.

In addition, certain provisions in our intellectual property agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or technology, or affect 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.

In addition, agreements with third parties typically restrict the ability of such third parties to publish data potentially relating to our trade secrets. Our academic collaborators typically have rights to publish data, provided that we are notified in advance and may delay publication for a specified period of time in order to secure our intellectual property rights arising from the arrangement. In other cases, publication rights are controlled exclusively by us, although in some cases we may share these rights with other parties. We also conduct joint research and product development activities that may require us to share trade secrets under the terms of our research and development collaborations or similar agreements. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using physical and technological security measures. Such measures may not provide adequate protection for our proprietary information. For example, our security measures may not prevent an employee or consultant with authorized access from misappropriating our trade secrets and providing them to a competitor, and the recourse we have available against such misconduct may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets. Furthermore, our proprietary information may be independently developed by others in a manner that could prevent legal recourse by us. Competitors could purchase any products we may develop and commercialize and attempt to reverse engineer and replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights or design around our protected technology. In addition, our key employees, consultants, suppliers or other individuals with access to our proprietary technology and know-how may incorporate that technology and know-how into projects and inventions developed independently or with third parties. As a result, disputes may arise regarding the ownership of the proprietary rights to such technology or know-how, and any such dispute may not be resolved in our favor. If any of our confidential or proprietary information, including our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed and such disclosure or misappropriation could have a material adverse effect on our business.

We will not seek to protect our intellectual property rights in all jurisdictions throughout the world, and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

Filing, prosecuting and defending patents on product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States, assuming that rights are obtained in the United States. In-licensing patents covering product candidates in all countries throughout the world may similarly be prohibitively expensive, if such opportunities are available at all. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions.

We generally apply for patents in those countries where we intend to make, have made, use, offer for sale or sell products and where we assess the risk of infringement to justify the cost of seeking patent protection. However, we do not seek protection in all countries where we sell products and we may not accurately predict all the countries where patent protection would ultimately be desirable. If we fail to timely file a patent application in any such country or major market, we may be precluded from doing so at a later date. Competitors may use our technologies in jurisdictions where we do not pursue and obtain patent protection to develop their own products and may export otherwise infringing products to territories where we have patent protection, but where our ability to enforce our patent rights is not as strong as in the United States. These products may compete with any products that we or our collaborators may develop, and our patents or other intellectual property rights may not be effective or sufficient to prevent such competition.

The laws of some other countries do not protect intellectual property rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. In addition, the legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to biopharmaceuticals or biotechnologies. As a result, many companies have encountered significant difficulties in protecting and defending intellectual property rights in certain jurisdictions outside the United States. Such issues may make it difficult for us to stop the infringement of our patents, if obtained, or the misappropriation of our other intellectual property rights. For example, many other countries, including countries in the EU, have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. 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 and could limit our potential revenue opportunities. Accordingly, our and our licensors' efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

Furthermore, proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, subject our patents to the risk of being invalidated or interpreted narrowly, subject our patent applications to the risk of not issuing or provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded to us, if any, may not be commercially meaningful, while the damages and other remedies we may be ordered to pay such third parties may be significant. 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.

We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in-licenses.

We have rights, through licenses from third parties and under patents that we own, to the intellectual property to develop the product candidates we are currently developing alone or with collaborators. Because our programs may involve additional product candidates that may require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights. In addition, product candidates may require specific formulations to work effectively and efficiently, and these rights may be held by others. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies, or companies that 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 to develop or commercialize product candidates. These established companies may have a competitive advantage over us due to their size and greater cash resources and clinical development and commercialization capabilities. We may not be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding product candidates that we may seek to acquire.

For example, 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 strategic alliance. Regardless of such right of first negotiation, we may be unable to negotiate a license within the specified time frame or under terms that are acceptable to us, and the institution may license such intellectual property rights to third parties, potentially blocking our ability to pursue our development and commercialization plans.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license to us intellectual property rights that we require in order to successfully develop and commercialize potential products. We also may be unable to obtain such a license or assignment on terms that would allow us to make an appropriate return on our investment. In either event, our business and prospects for growth could suffer.

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.

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. We may not be able to protect our rights to our trademarks and trade names, which we need to build name recognition among potential collaborators or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our unregistered trademarks or trade names. Over the long term, if we are unable to successfully register our trademarks and trade names and establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights and other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

Risks Related to Owning Our Common Stock

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant to us as a clinical-stage biopharmaceutical company, as our stock price can significantly fluctuate as a result of public announcements regarding the progress of our development efforts for our discovery platform and our product candidates. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

We do not currently intend to pay dividends on our common stock.

We do not intend to pay any dividends to holders of our common stock for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. In addition, pursuant to our loan and security agreement with PWB we are prohibited from paying cash dividends without the prior written consent of PWB and future debt instruments may materially restrict our ability to pay dividends on our common stock. Therefore, you are not likely to receive any dividends on your common stock for the foreseeable future, and the success of an investment in our common stock will depend upon any future appreciation in its value. Consequently, you may need to sell all or part of your common stock after price appreciation, which may never occur, as the only way to realize any future gains on your investment.

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

Provisions in our amended and restated certificate of incorporation and our restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions include those establishing:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from filling vacancies on our board of directors;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the ability of our board of directors to alter our bylaws without obtaining stockholder approval;

- the required approval of the holders of at least two-thirds of the shares entitled to vote at an election of directors to adopt, amend or repeal our bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;

- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;

- the requirement that a special meeting of stockholders may be called only by the chairman of the board of directors, our chief executive officer (or our president, in the absence of a chief executive officer) or a majority of our board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and

- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our amended and restated certificate of incorporation and our amended and restated bylaws include exclusive forum provisions 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 to the fullest extent permitted by law, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim for breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (3) any action asserting a claim arising pursuant to any provision of the General Corporation Law of the State of Delaware, our amended and restated certificate of incorporation or our amended and restated bylaws, or (4) any action asserting a claim governed by the internal affairs doctrine. Under our amended and restated certificate of incorporation, this exclusive forum provision will not apply to claims which are vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery of the State of Delaware, or for which the Court of Chancery of the State of Delaware does not have subject matter jurisdiction. For instance, the provision would not apply to actions arising under federal securities laws, including suits brought to enforce any liability or duty created by the Exchange Act or the rules and regulations thereunder. Further, our amended and restated bylaws provide that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States will be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act and that any person or entity purchasing or otherwise acquiring or holding any interest in shares of our capital stock are deemed to have notice of and consented to this provision. These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. For example, stockholders who do bring a claim in the Court of Chancery could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near the State of Delaware. The Court of Chancery may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments or results may be more favorable to us than to our stockholders.

We are an "emerging growth company" and a "smaller reporting company," and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. We will remain an emerging growth company until the earlier of (1) December 31, 2024, (2) the last day of the fiscal year in which we have total annual gross revenue of $1.07 billion or more, (3) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years, or (4) the date on which we are deemed to be a large accelerated filer under the rules of the SEC which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to present only two years of "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this Quarterly Report on Form 10-Q;

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations in our SEC filings regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have elected to take advantage of this extended transition period.

We are also a smaller reporting company, and we will remain a smaller reporting company until the fiscal year following the determination that our voting and non-voting common stock held by non-affiliates is more than $250 million measured on the last business day of our second fiscal quarter, or our annual revenues are more than $100 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is more than $700 million measured on the last business day of our second fiscal quarter. Similar to emerging growth companies, smaller reporting companies are able to provide simplified executive compensation disclosure and have certain other reduced disclosure obligations, including, among other things, being required to provide only two years of audited financial statements and not being required to provide selected financial data, supplemental financial information or risk factors.

We may choose to take advantage of some, but not all, of the available exemptions for emerging growth companies and smaller reporting companies. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be reduced or more volatile.

General Risk Factors

We or third parties with whom we have relationships may be adversely affected by natural or manmade disasters, public health emergencies and other natural catastrophic events, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Natural or manmade disasters could severely disrupt our operations and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, public health emergency, power outage or other event occurred that prevented us from using all or a significant portion of our facilities, that damaged our infrastructure or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time, and our research and development activities could be setback or delayed. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business, and such an event could disrupt our operations, cause us to incur remediation costs, damage our reputation and cause a loss of confidence in us and our or third parties' ability to conduct clinical trials, which could adversely affect our reputation and delay our research and development programs.

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

Global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability, and similar deterioration in the credit and financial markets and confidence in economic conditions may occur in the future. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, 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 and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers or others with whom we have strategic relationships may not survive any difficult economic times, which could directly affect our ability to attain our operating goals.

As of March 31, 2021, we had cash and cash equivalents of $193.5 million. While we are not aware of any downgrades, material losses or other significant deterioration in the fair value of our cash equivalents since March 31, 2021, deterioration of the global credit and financial markets could negatively impact our current portfolio of cash equivalents or our ability to meet our financing objectives. Furthermore, our stock price may decline due in part to the volatility of the stock market and any general economic downturn.

The market price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock.

The market price of our common stock is likely to be highly volatile and may fluctuate substantially due to many factors, including:

- inconsistent trading volume levels of our common stock;
- announcements or expectations regarding debt or equity financing efforts;
- sales of common stock by us, our insiders or our other stockholders;
- actual or anticipated fluctuations in our financial condition and operating results;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- results from or delays in our studies or trials, or those of our collaborators, competitors or companies perceived to be similar to us;
- delay, failure or discontinuation of any of our product development and research programs, or those of our collaborators, competitors or companies perceived to be similar to us;
- announcements about new research programs or product candidates from us or our collaborators, our competitors or companies perceived to be similar to us;
- announcements by us, our collaborators, our competitors or companies perceived to be similar to us relating to significant acquisitions, strategic partnerships or alliances, joint ventures, collaborations or capital commitments;
- actual or anticipated changes in our growth rate relative to our competitors or companies perceived to be similar to us;
- fluctuations in the valuation of our collaborators, our competitors or companies perceived to be comparable to us;
- a lack of, limited or withdrawal of coverage by security analysts, or positive or negative recommendations by them;
- actual or expected changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- publication of research reports about us, genome editing or the biopharmaceutical and agricultural biotechnology industries;
- developments or changing views regarding the use of genomic products, including those that involve genome editing;
- our ability to effectively manage our growth;
- the recruitment or departure of key personnel;
- the results of any efforts by us to identify, develop, acquire or in-license additional product candidates, products or technologies;
- unanticipated serious safety concerns related to the use of any of our product candidates, or those of our competitors or companies perceived to be similar to us;
- the termination of a collaboration agreement, licensing agreement or other strategic arrangement or the inability to establish additional strategic arrangements on favorable terms, or at all;
- regulatory actions with respect to any of our product candidates, or those of our competitors or companies perceived to be similar to us;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- regulatory or legal developments in the United States and other countries;
- changes in physician, hospital, healthcare provider or agricultural practices that may make our or our collaborators' products less useful;
- changes in the structure of healthcare payment systems;
- significant lawsuits, such as products liability, patent or stockholder litigation;

- short sales of our common stock; and
- general economic, industry and market conditions.

These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance. These factors may have a material adverse effect on the market price and liquidity of our common stock, which may limit or prevent you from readily selling your shares of common stock and may affect our ability to obtain financing or enter into desired strategic relationships.

If securities or industry analysts issue an adverse or misleading opinion regarding our common stock, our stock price and trading volume could decline.

The trading market for our common stock relies in part on the research and reports that industry or securities analysts publish about us or our business. We do not control these analysts. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our preclinical studies and clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed/Furnished Herewith
3.1	Amended and Restated Certificate of Incorporation of Precision BioSciences, Inc.	8-K	001-38841	3.1	4/1/2019	
3.2	Amended and Restated Bylaws of Precision BioSciences, Inc.	8-K	001-38841	3.2	4/1/2019	
10.1†	Program Purchase Agreement by and between Les Laboratoires Servier, Institut de Recherches Internationales Servier and Precision BioSciences, Inc., dated April 9, 2021.					*
10.2#	Employment Agreement between Precision BioSciences, Inc. and Alan List, dated April 26, 2021					*
10.3#†	Consulting Agreement between Precision BioSciences, Inc. and Christopher Heery, M.D., dated April 23, 2021.					*
10.4#	Non-Employee Director Compensation Plan (as amended)					*
10.5	Fourth Amendment to Lease, dated May 4, 2021, to Lease Agreement between Precision BioSciences, Inc. and Durham TW Alexander, LLC, dated October 2, 2018, as amended.					*
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					*
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					*
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					**
32.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					**
101.INS	XBRL Instance Document					*
101.SCH	XBRL Taxonomy Extension Schema Document					*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					*
101.LAB	XBRL Taxonomy Extension Label Linkbase Document					*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					*

* Filed herewith.

** Furnished herewith.

† Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

# Denotes a management contract or compensation plan or arrangement.

SIGNATURES

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

Precision BioSciences, Inc.

Date: May 13, 2021

By: /s/ Matthew Kane

Matthew Kane
President, Chief Executive Officer and Director
(principal executive officer and authorized signatory)

Date: May 13, 2021

By: /s/ John Alexander Kelly

John Alexander Kelly
Interim Chief Financial Officer
(principal financial officer)

Exhibit 10.1

Certain information marked as [***] has been excluded from this exhibit because it is both not material and is the type that the registrant treats as private or confidential

PROGRAM PURCHASE AGREEMENT

THIS PROGRAM PURCHASE AGREEMENT (this "Agreement"), effective as of April 9, 2021 (the "Effective Date"), is made and entered into by and among LES LABORATOIRES SERVIER, a corporation incorporated under the laws of France having a principal place of business at 50 rue Carnot, 92150 Suresnes, France ("LLS") and INSTITUT DE RECHERCHES INTERNATIONALES SERVIER, a corporation incorporated under the laws of France having its principal place of business at 50 rue Carnot, 92150 Suresnes, France ("IRIS") (LLS and IRIS together jointly and severally, "Servier"), and PRECISION BIOSCIENCES, INC., a Delaware corporation with its principal place of business at 302 E Pettigrew St A-100, Durham, NC 27701, U.S.A. ("Precision"). Precision and Servier may each be referred to herein individually as a "Party" and collectively as the "Parties."

RECITALS

WHEREAS, the Parties previously entered into that certain Development and Commercial License Agreement, effective February 24, 2016 (as previously amended by that certain Amendment No. 1 to Development and Commercial License Agreement, effective as of February 24, 2017, that certain Amendment No. 2 to Development and Commercial License Agreement, effective as of August 21, 2017, that certain Amendment No. 3 to Development and Commercial License Agreement, effective as of February 5, 2018, that certain Amendment No. 4 to Development and Commercial License Agreement, effective as of May 23, 2018 ("Amendment No. 4"), that certain Amendment No. 5 to Development and Commercial License Agreement, effective as of September 18, 2019, and that certain Amendment No. 6 to the Development and Commercial License Agreement, effective as of October 2, 2020 (the "DCLA").

WHEREAS, Servier desires to divest the Reversion Program (as defined in Section 1.12).

WHEREAS, Precision desires to re-acquire the rights under the Reversion Program.

WHEREAS, the Parties desire to terminate the DCLA by mutual consent in accordance with Section 14.2.6 of the DCLA as amended by this Agreement, under the terms and conditions set forth herein.

NOW THEREFORE, in consideration of the mutual promises and covenants set forth below and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

1. DEFINITIONS

The following terms as used in this Agreement shall have the meanings set forth in this Article 1. Capitalized terms used in this Agreement without being defined herein shall have the meaning set out in the DCLA.

1.1. "Biosimilar Product" means, with respect to a Product, and on a Product-by-Product and country-by-country basis, any product (including a "generic product," "biogeneric," "follow-on biologic," "follow-on biological product," "follow-on protein product," "similar biological medicinal product," or "biosimilar product") approved by way of an abbreviated regulatory mechanism by the relevant Regulatory Authority in a country in reference to such Product, that is sold in the same country (or is commercially available in the same country via import from another country) as such Product by any Third Party and that (a) in the United States, is subject to a license by the FDA under Section 351(k) of the PHSA as a product that is "biosimilar" (as defined in Section 351(i)(2) of the PHSA) to, or "interchangeable" (as defined in Section 351(i)(3) of the PHSA) with, such Product, (b) in the EU, has been licensed as a similar biological medicinal product by the EMA pursuant to Directive 2001/83/EC, as may be amended, or any subsequent or superseding law, statute or regulation, or (c) in any country outside the United States and the EU, has received Marketing Approval in an abbreviated licensure procedure by the applicable Regulatory Authority in such country as a product that is "interchangeable," "bioequivalent," "biosimilar" or other term of similar meaning, with respect to the Product and in reliance upon the prior Marketing Approval (or data therein) of such Product, as is necessary to permit substitution of such product for the Product under applicable Law in such country.

1.2. "First Commercial Sale" means with respect to a particular Product in a particular country or other jurisdiction, the first arms'-length sale of such Product by Precision or any of its Affiliates or under their authority, e.g. a distributor (the "Selling Entity") or by the Product Partner with respect to a Product Partnering Transaction, in each case to a Third Party for use in the Field in such country or other jurisdiction after such Product has been granted (a) Marketing Approval and, if necessary to sell the Product to a Third Party, a Reimbursement Approval if such sale is in any country in the EU or (b) Marketing Approval only if such sale is not in a country in the EU. For avoidance of doubt, no sale or other disposition of a Product shall be deemed the "First Commercial Sale" if such sale or other disposition would not be included in the calculation of Net Sales.

1.3. "First Indication" means, [***]

1.4. "Independently Active Therapeutic Ingredient" means, with respect to a Combination Product, an active therapeutic ingredient having a different Target or mode of action, or which is otherwise treated or designated by the applicable Regulatory Authority as a separate active ingredient, than the applicable Product.

1.5. "Net Sales" means the [***] of monies invoiced by Precision or any Selling Entity, for the sale, use or other disposition of a Product to Third Parties less the following amounts in Sections 1.5.1 through 1.5.13 below (the "Permitted Deductions"):

[***]

The amounts invoiced by Precision, or any Selling Entity for [***] shall not be included in the computation of Net Sales hereunder and Net Sales shall be the [***]

Further, the following shall not be considered Net Sales: [***]

In the event a Product is co-packaged, co-formulated, sold in conjunction with or otherwise sold in a manner that includes one or more Independently Active Therapeutic Ingredients in addition to a Product (such Product, a "Combination Product"), then Net Sales, for purposes of determining royalty payments on such Combination Product, will be calculated by [***]

1.6. "Other Targets" means [***]

1.7. [***]

1.8. "Product" means any of the following: (a) the CAR-T product known as PBCAR0191 Directed to CD19, (b) the CAR-T product known as PBCAR19B Directed to CD19, (c) the CAR-T product known as [***], (d) the CAR-T product known as [***], (e) the CAR-T product known as [***], (f) the CAR-T product known as [***], in each case as described in the applicable Development Plan as of immediately prior to the Effective Date of this Agreement as such product may be further developed thereafter [***] and (g) the first one (1) CAR-T product for which IND Acceptance occurs constituting a Variant (not described in Section 1.8 (a) to (f)) Directed to CD19 or Directed to any Other Target.

1.9. "Product Partnering Transaction" means a transaction pursuant to which Precision or any of its Affiliates grants to a Third Party (such Third Party, a "Product Partner") [***]

1.10. "Proceeds" means sums received by Precision from a Product Partner as consideration for any Product Partnering Transaction, including [***]. Proceeds received as consideration for any Product Partnering Transaction that are not clearly allocated to a Product or other Targets subject to such Partnering Transaction shall be allocated [***]. In the event that Servier disputes in good faith [***] during such [***] period, the Parties shall endeavor to solve the dispute amicably and promptly by [***]. If a Party provides written notice to the other Party regarding any such dispute and such dispute is not resolved through [***] such dispute shall be resolved in accordance with the procedures set forth in Schedule 4.

1.11. "Reimbursement Approval" means with respect to a particular Product and a particular country or regulatory jurisdiction, any pricing and reimbursement approvals by the applicable Regulatory Authority or other Governmental Authority in such country or regulatory jurisdiction that are necessary for a sale or transfer of such Product to any applicable Regulatory Authority or other Governmental Authority, or for a sale or

transfer of such Product to be reimbursable or credited by, charged to or otherwise paid for by, in whole or in part, any applicable Regulatory Authority or other Government Authority in such country or regulatory jurisdiction at the relevant time.

1.12. "Reversion Program" means (a) any product that (i) was a Licensed Product Candidate immediately prior to the Effective Date of this Agreement and (ii) is no longer a Licensed Product Candidate as a result of this Agreement, (b) any Included Target that was an Included Target immediately prior to the Effective Date of this Agreement and is no longer an Included Target as a result of this Agreement, and (c) any other engineered human T cells with Chimeric Antigen Receptors Directed to any Target that was an Included Target immediately prior to the Effective Date of this Agreement and is no longer an Included Target as a result of such termination ((a), (b) and (c) being listed in Schedule 1 to this Agreement), and (d) all rights and obligations under the DCLA, including rights granted to Servier under Article IV of the DCLA.

1.13. "Royalty Term" shall have the meaning set forth in Section 3.7.

1.14. "Second Indication" means, [***]

1.15. "Selling Entity" has the meaning set forth in Section 1.2.

1.16. "Third Party License Agreement" means any agreement (including any settlement agreement) entered into after the Effective Date with a Third Party, whereby royalties are to be paid to such Third Party based on the grant of rights under Patent Rights Controlled by such Third Party in a country or countries, which Patent Rights are Necessary to Commercialize the Product. For purposes of this definition, "Necessary to Commercialize" means, with respect to a particular Product and Patent Rights Controlled by a Third Party in a particular country or countries, [***]. In the event Servier in good faith disputes the determination by Precision that such Patent Rights are Necessary to Commercialize, such dispute shall be resolved in accordance with Section 8.4.

1.17. "Upfront Fee" has the meaning set forth in Section 3.1.

1.18. "Waiver Fee" has the meaning set forth in Section 3.2.

1. AMENDMENT TO SECTION 14.2 OF THE DCLA

The following new sub-section is hereby added to Section 14.2 of the DCLA (Early Termination):

14.2.6 By Mutual Consent. This Agreement may be terminated by the mutual written consent of the Parties.

2. EFFECTS OF TERMINATION OF THE DCLA

2.1. The Parties hereby terminate the DCLA, as amended by this Agreement, by mutual consent in accordance with Section 14.2.6 of the DCLA and under the terms and conditions set forth herein.

2.2. All licenses and options to license granted to either Party under the DCLA, including all sublicenses thereunder, are hereby immediately terminated.

2.3. Except with respect to the surviving obligations set forth in Article 5 of this Agreement, each of the Parties is hereby released from its obligations under the DCLA, including with respect to the Reversion Program.

2.4. Within [***] following the Effective Date of this Agreement, Servier shall, at the request of Precision, (i) deliver to Precision (and if delivery is not feasible, certify the destruction of) any and all tangible Confidential Information of Precision in Servier's possession, (ii) remove Confidential Information of Precision relating to the manufacturing and Regulatory Filings for the Product known as PBCAR19B from all databases and systems, without regard for whether such removal is practicable, and (iii) to the extent practicable, remove any other Confidential Information of Precision from all databases and systems and in those instances where removal is not practicable, segregate or otherwise indicate that such Confidential Information is restricted. Servier represents and warrants that it has no Confidential Information of Precision in its lab notebooks. Servier shall have the right to retain one (1) copy of Precision's Confidential Information described in sub-part (iii) above in its archives solely for the purpose of maintaining compliance with its obligations hereunder.

2.5. The Parties hereby acknowledge and agree that no payment or other liability or obligation has accrued under the DCLA (other than such payments as subject to the Waiver Fee set forth in Section 3.2 and the surviving obligations set forth in Article 5 of this Agreement) prior to or on the Effective Date of this Agreement.

2.6. The Parties hereby acknowledge and agree that Section 2.6 of the DCLA was removed from the DCLA pursuant to Amendment No. 4, therefore the license set forth in Section 2.6.1 of the DCLA has never been entered into between the Parties and Precision has no right to request in writing to enter into an agreement pursuant to which Precision may use Isolex Platform Technology in connection with Products.

2.7. Servier represents and warrants that Servier and its Affiliates do not Control any Patents or Know-How (that came to be Controlled as a result of activities in connection with the DCLA) that are reasonably necessary or useful in connection with the Development, manufacture, use or Commercialization of Products in the Territory and that on the Effective Date of this Agreement, Precision Controls all Know-How, Inventions, Patents, all materials, documents, licenses, Third Party agreements, preclinical and clinical data, safety data and all other supporting data, Regulatory Filings, and manufacturing processes with respect to the Reversion Program. Accordingly, the Parties hereby acknowledge and agree that Section 14.3.1(a) of the DCLA is not applicable and Precision hereby releases Servier from all its obligations under Section 14.3.1(a) of the DCLA; provided, however, to the extent the representation and warranty in the first sentence of this Section 2.7 is found untrue by an arbitral award rendered in accordance with Section 8.4, then effective upon the Effective Date Servier agrees to (i) grant and hereby grants to Precision and its Affiliates a royalty-free, non-exclusive, worldwide, transferrable, irrevocable license (with the right to grant sublicenses through multiple tiers) under any such Patents or Know-How (that came to be Controlled as a

result of activities in connection with the DCLA) to make, have made, use, sell, offer for sale, import and otherwise Develop and Commercialize Products (or any other engineered human T Cells with Chimeric Antigen Receptors Directed to CD19 or any Other Targets) in the Field in the Territory and (ii) make such assignments as necessary to accomplish the intended effect of Section 14.3.1(a) of the DCLA.

3. PAYMENTS

3.1. Upfront Payment. In consideration of Servier's contribution to the progress of the Reversion Program as of the Effective Date, Precision shall pay to Servier, on or prior to the date that is [***] after the Effective Date or, if such date is not a Business Day, on the next Business Day, a one time, non-refundable, non-creditable fee equal to one million two hundred and fifty thousand USD ($1,250,000) (the "Upfront Fee"). Servier shall invoice Precision for the Upfront Fee on the Effective Date.

3.2. Waiver Fee. In consideration of Servier's contribution to the progress of the Reversion Program as of the Effective Date, Precision shall forever waive Servier's obligations to pay the amounts set forth below otherwise payable by Servier under Section 8.3.1(a) of the DCLA in the absence of termination of the DCLA (the "Waiver Fee").

Phase I Success for the Licensed Product Candidate PBCAR0191	$ [***]
Additional milestone payment upon Phase I Success for the Licensed Product Candidate PBCAR0191	$ [***]
First Gene Editing Event for the Licensed Product Candidate Directed to [***]	$ [***]
First Gene Editing Event for the Licensed Product Candidate Directed to [***]	$ [***]
Total Waiver Fee	**$ 18,750,000**

3.3. Milestone Payments. In addition, Precision or any of its Affiliates shall, solely to the extent Precision or such Affiliate has not entered into a Product Partnering Transaction with respect to the applicable Product (in which case solely the payment obligations set forth in Section 3.5 shall apply with respect to the scope of such Product Partnering Transaction), and conditioned upon achievement of the applicable milestone or event, for each Product, make the following payments to Servier in consideration of Servier's contribution to the progress of the Reversion Program as of the Effective Date:

REGULATORY AND COMMERCIAL MILESTONES for the first Product Directed to CD19	
[***]	$ [***]
[***]	$ [***]
[***]	$ [***]
[***]	$ [***]
[***]	$ [***]
[***]	$ [***]
[***]	$ [***]
Sub-total	**$ [***]**

SALES MILESTONE PAYMENTS for the first Product Directed to CD19	
$[***] of global Net Sales of the first Product Directed to CD19 to achieve such sales level in a Calendar Year	$ [***]
$[***] of global Net Sales of the first Product Directed to CD19 to achieve such sales level in a Calendar Year	$ [***]
$[***] of global Net Sales of the first Product Directed to CD19 to achieve such sales level in a Calendar Year	$ [***]
Sub-total	**$ [***]**

For clarity, the maximum total milestones payable for all Products Directed to CD19 shall be $[***], regardless of whether such milestones are achieved by one or both of the Products Directed to CD19.

REGULATORY AND COMMERCIAL MILESTONES for each Product Directed to Other Targets	
[***]	$ [***]
[***]	$ [***]
[***]	$ [***]
[***]	$ [***]
[***]	$ [***]
[***]	$ [***]
Sub-total	**$ [***]**

SALES MILESTONE PAYMENTS for each Product Directed to Other Targets	
$[***] of global Net Sales of the Product in a Calendar Year	$ [***]
$[***] of global Net Sales of the Product in a Calendar Year	$ [***]
$[***] of global Net Sales of the Product in a Calendar Year	$ [***]
Sub-total	**$ [***]**

For clarity, the maximum total milestones payable for all Products Directed to Other Targets shall be $[***]

Each milestone payment set forth in this Section 3.3 shall be payable by Precision upon the first achievement of the applicable milestone, and Precision shall provide notice to Servier of such achievement within [***] following such achievement. Following Servier's receipt of a notice described in the immediately preceding sentence, Servier shall provide Precision with a corresponding invoice and Precision shall pay to Servier the applicable milestone payment described above within [***] after receipt of such invoice.

3.4. Royalties. In addition, in consideration of Servier's contribution to the progress of the Reversion Program as of the Effective Date, on a Product-by-Product basis, Precision or any of its Affiliates shall, solely to the extent Precision or such Affiliate has not entered into a Product Partnering Transaction with respect to the applicable Product (in which

case solely the payment obligations set forth in Section 3.5 shall apply with respect to the scope of such Product Partnering Transaction), pay to Servier non-creditable, non-refundable royalty payments at the following royalty rates on the applicable portion of cumulative Calendar Year global Net Sales of the applicable Product:

ROYALTIES	
For each Product Directed to [***]	[***]%
For each Product Directed to [***]	[***]%
For each Product Directed to [***]	[***]%
For each Product Directed to [***]	[***]%

3.5. In consideration of Servier's contribution to the progress of the Reversion Program as of the Effective Date, should Precision enter into a Product Partnering Transaction with respect to a particular Product, Precision shall (i) provide Servier with a written notice no later than [***] after entering into such Product Partnering Transaction and (ii) in lieu of any payments under Section 3.3 or Section 3.4 with respect to the scope of such Product Partnering Transaction, make the following payments to Servier:

REGULATORY MILESTONE any Product Directed to CD19	
[***]	$ [***]

For clarity, the above payment for a Product Directed to CD19 shall be payable one time upon the first achievement of such milestone by any Product Directed to CD19, in accordance with the invoice procedures set forth in Section 3.3, even if Precision has entered into a Product Partnering Transaction for such Product prior to the achievement of such milestone, but such milestone shall not be payable under this Section 3.5 if it has already been paid by Precision under Section 3.3.

Proceeds with respect to a Product Partnering Transaction with respect to a Product Directed to [***]	[***]% of any Proceeds, which Proceeds [***]
Proceeds with respect to a Product Partnering Transaction with respect to a Product Directed to [***]	[***]% of any Proceeds, which Proceeds [***]
Proceeds with respect to a Product Partnering Transaction with respect to a Product Directed to [***]	[***]% of any Proceeds, which Proceeds [***]
Proceeds with respect to a Product Partnering Transaction with respect to a Product Directed to [***]	[***]% of any Proceeds, which Proceeds [***]

3.6. Diligence obligation. Should Precision enter into a Product Partnering Transaction with respect to a Product Directed to CD19 or a Product Directed to any Other Target, [***].

3.7. Royalty Term. Precision's obligation to make (a) royalty payments pursuant to Section 3.4 with respect to a particular Product and (b) Proceeds payments pursuant to Section 3.5 with respect to a Product Partnering Transaction with respect to a particular Product, shall each expire, on a Product-by-Product basis, ten (10) years after the first to occur of the First Commercial Sale of such Product in the U.S. or any Major EU Country; provided, however, if such Product is first sold in a country other than the U.S. or any Major EU Country prior to the First Commercial Sale in the U.S. or any Major EU Country, Precision's obligation to make (i) royalty payments pursuant to Section 3.4

with respect to such Product in such other country and (ii) Proceeds payments pursuant to Section 3.5 with respect to a Product Partnering Transaction for such Product with respect to such other country shall expire ten (10) years after the First Commercial Sale of such Product in such other country (all of the foregoing, as applicable with respect to a particular Product, the "Royalty Term").

3.8. Royalty Stacking. Subject to the terms herein, if Precision or its Affiliate enters into one or more Third Party License Agreement(s) with respect to a particular Product in a particular country or countries, then Precision's obligation to pay royalties to Servier pursuant to Section 3.4 with respect to sales of such Product in such country or countries in a particular Calendar Quarter shall be reduced by [***] of the amount of the royalties paid by Precision or its Affiliate to such Third Party pursuant to such Third Party License Agreement for such sales, provided that no royalty payment to Servier for a Product hereunder shall be reduced, pursuant to this Section 3.8, to less than [***] of the royalty payment that would otherwise be due to Servier in the absence of a reduction pursuant to this Section 3.8.

3.9. Biosimilar Products. On a country-by-country and Product-by-Product basis, upon the first commercial sale of one or more Biosimilar Products with respect to a Product in any country in the Territory during the Royalty Term, the royalty rates pursuant to Section 3.4 with respect to sales of such Product will be permanently reduced in such country by [***] (in addition to any reductions in Section 3.8) from the date of first commercial sale of such Biosimilar Product(s) in such country.

3.10. Royalty Payment Timing; Royalty Reports. Within [***] following the end of each Calendar Quarter during which (a) royalty payments accrue pursuant to Section 3.4 with respect to a particular Product or (b) Proceeds payments accrue pursuant to Section 3.5 with respect to a Product Partnering Transaction with respect to a particular Product, Precision shall provide Servier with a Sales Report and any other information reasonably required by Servier for the purpose of calculating royalties, Proceeds payments and sales milestone payments due under this Agreement. Any royalty payments and Proceeds payments due to Servier will be paid on the date of delivery of such Sales Report. In the event that either Party determines that the calculation of Net Sales for a Calendar Quarter deviates from the amounts previously reported to Servier for any reason (such as, on account of additional amounts collected or Product returns), Precision and Servier shall reasonably cooperate to reconcile any such deviations to the extent necessary under applicable legal or financial reporting requirements.

3.11. Audit. Until the expiration of all royalty payment obligations hereunder and for a period of [***] thereafter, Precision shall keep complete and accurate records pertaining to the sale or other disposition of Products by Precision and its Affiliates in sufficient detail to permit Servier to confirm the accuracy of the royalties and sales milestone payments due hereunder. Servier shall have the right to cause an independent internationally recognized accounting firm reasonably acceptable to Precision to audit such records for the sole purpose of confirming Net Sales and royalties for a period covering not more than the preceding [***]. Precision may require such accounting firm to execute a reasonable confidentiality agreement with Precision prior to commencing the audit. Such audits may be conducted during normal business hours upon reasonable prior

written notice to Precision, but no more frequently than once per year. No accounting period of Precision shall be subject to audit more than one time by Servier, unless after an accounting period has been audited by Servier, Precision restates its financial results for such accounting period, in which event Servier may conduct a second audit of such accounting period in accordance with this Section 3.11. Adjustments (including remittances of underpayments or overpayments disclosed by such audit) shall be made by the Parties to reflect the results of such audit, which adjustments shall be paid (plus interest as set forth in Section 3.13) promptly following receipt of an invoice therefor. Servier shall bear the full cost and expense of such audit unless such audit discloses an underpayment by Precision of [***] or more of the amounts due under this Agreement for the audited period, in which case Precision shall bear and reimburse Servier for the full cost and expense of such audit.

3.12. Taxes. All payments under this Agreement shall be made without any deduction or withholding for or on account of any tax, except as set forth in this Section 3.12. The Parties agree to cooperate with one another and use reasonable efforts to minimize under applicable Law obligations for any and all income or other taxes required by applicable Law to be withheld or deducted from any of the royalty and other payments made by or on behalf of a Party hereunder ("Withholding Taxes"). Precision shall, if required by applicable Law, deduct from any amounts that it is required to pay to the recipient Party hereunder an amount equal to such Withholding Taxes; provided that Precision shall give Servier reasonable notice prior to paying any such Withholding Taxes. Such Withholding Taxes shall be paid to the proper taxing authority for Servier's account and, if available, evidence of such payment shall be secured and sent to Servier within [***] after such payment. Precision shall, at Servier's sole cost and expense, as mutually agreed by the Parties, do all such lawful acts and sign all such lawful deeds and documents as the Recipient Party may reasonably request to enable the Parties to avail themselves of any applicable legal provision or any double taxation treaties with the goal of paying the sums due to Servier hereunder without deducting any Withholding Taxes. For US federal income tax purposes, Precision will report the payments made under this Agreement in the manner required by the US Internal Revenue Code (the "Code"). The Parties agree that this Agreement does not constitute a financial option for US federal income tax purposes as described in section 1234 of the Code.

3.13. Late Payments. If Servier does not receive payment of any sum due to it under this Agreement on or before the due date, interest shall thereafter accrue on the sum due to Servier from the due date until the date of payment, such interest to be calculated at a rate equal to the lesser of (a) [***] percent ([***]%) for each month during the period from the time any payment was due until paid in full, and (b) the highest rate permitted by applicable Laws.

3.14. Reporting. All financial reporting hereunder shall be, if applicable, on the basis of U.S. GAAP, consistently applied.

3.15. Currency; Exchange Rate. All payments to be made under this Agreement shall be made in USD by bank wire transfer in immediately available funds to a bank account designated by written notice from Servier. With respect to sales not denominated in USD, Precision shall convert each applicable quarterly sales in foreign currency into

USD by using the then current and reasonable standard exchange rate methodology applied by Precision in its worldwide accounting practices, consistent with U.S. GAAP, consistently applied. Based on the resulting sales in USD, the then applicable royalties shall be calculated. The initial wire transfer instructions for Servier are set forth on Schedule 2.

4. RIGHT OF FIRST NEGOTIATION

4.1. During the ROFN Term, in the event that Precision desires to engage in a bona fide process designed to enter into [***] or receives a bona fide written offer from a Third Party to enter into negotiations for [***] with respect to any Product Directed to CD19 (each a "ROFN Product"), Precision agrees to provide Servier with written notice of its intent to engage in such process, or that it intends to accept or negotiate with respect to such offer, as applicable (the "Precision ROFN Notice"). [***] Servier shall notify Precision in writing (the "Servier ROFN Election Notice") within [***] of Servier's receipt of the Precision ROFN Notice if Servier desires to exercise its right to negotiate with Precision the terms of [***] with respect to such ROFN Product (such license is referred to herein as the "Commercialization License"). The "ROFN Term" shall commence upon [***] and end upon [***] Following Precision's receipt of the Servier ROFN Election Notice, and solely in the event that [***] the Parties agree to negotiate in good faith regarding the main terms of a Commercialization License for a period of [***] following delivery of the Servier ROFN Election Notice by Servier (which may be extended upon mutual agreement of the Parties) (the "Negotiation Period"). For the avoidance of doubt, each Party is free to negotiate for any and all terms of a Commercialization License that such Party believes in good faith are appropriate and in such Party's best interest. Neither Party is required under this Article 4 to agree upon any terms of or to enter into any agreement for a Commercialization License.

4.2. [***]

4.3. [***]

4.4. [***]

5. **AMENDMENT TO SECTION 14.3.4 OF THE DCLA**

Section 14.3.4 of the DCLA is hereby amended as follows:

14.3.4 Survival. The following Articles and Sections of this Agreement, as well as remedies for breach of this Agreement, shall survive expiration or termination of this Agreement for any reason: ARTICLE I (solely to the extent required to enforce any other surviving rights or obligations of the Parties), Section 4.5, Section 9.1, Section 12.1, Section 12.2, Section 12.4.2, Section 12.4.5, ARTICLE XIII and Section 14.3.4.

Without limiting the foregoing, survival of Section 12.1 of the DCLA additionally means that all information disclosed by Precision to Servier under this Agreement shall be treated as Confidential Information of Precision under the provisions of Section 12.1 of the DCLA for the term of this Agreement. For the avoidance of doubt, Section 13.4.1 of the DCLA shall apply to activities

arising out of this Agreement as if fully set forth herein, provided that the reference to Article XII in Section 13.4.1 of the DCLA shall be replaced by Section 12.1, Section 12.2, Section 12.4.2, and Section 12.4.5.

6. PRESS RELEASE; DISCLOSURES OF TERMS OF AGREEMENT

6.1. Precision shall have the right to issue an initial press release with respect to this Agreement promptly after the Effective Date. Precision shall submit to Servier the draft initial press release for review and comments at least [***] prior to issuing such initial press release. Precision shall take into account any comments Servier may have in relation to the initial press release to the extent such comments relate to Servier's Confidential Information. The Parties have agreed upon certain paragraphs attached hereto as Schedule 3, which with respect to Precision may be incorporated into any press release, including Precision's initial press release regarding the Products, in Precision's sole discretion. Servier shall refrain from making any statement, public or otherwise, regarding any Products or the Reversion Program unless Servier is required to make such statement pursuant to applicable Law, such statement is limited to the fact that Servier is no longer Developing or Commercializing the Products, or Precision shall have approved any such statement in writing. For clarity, subsequent public announcements, publications and press releases regarding Precision's Development and Commercialization of the Products and conduct of the Reversion Program may be made by Precision in its sole discretion unless such subsequent public announcements, publications and press releases regarding Precision's Development and Commercialization of the Products and conduct of the Reversion Program contain Servier's Confidential Information or any reference to Servier.

6.2. Notwithstanding the foregoing, (a) either Party may disclose the relevant terms of this Agreement: (i) to the extent required or advisable to comply with the rules and regulations promulgated by the U.S. Securities and Exchange Commission or any equivalent governmental agency, provided that in the event that a copy of this Agreement will be filed with any such agency, such Party shall submit a confidential treatment request in connection with such disclosure and shall submit with such confidential treatment request only such redacted form of this Agreement, which redacted form of this Agreement shall be provided to the other Party for review and comment within no less than [***] from the date of notice to the non-disclosing Party and which comments shall be considered in good faith by the disclosing Party; and (ii) upon request from a Governmental Authority (such as a tax authority), provided the disclosing Party uses reasonable efforts to ensure the Governmental Authority maintains such terms as confidential; and (b) Precision may disclose the relevant terms of this Agreement to the extent necessary for Precision to exercise rights under this Agreement, to any actual or potential licensee, or acquirer of Precision.

7. TERM AND TERMINATION

7.1. Term. This Agreement shall become effective as of the Effective Date and shall be perpetual, irrevocable and non-terminable. Neither Party shall have any right to cancel, revoke or terminate this Agreement or any license or right granted by either Party to the other Party in or pursuant to this Agreement.

8. MISCELLANEOUS

8.1. Assignment. This Agreement is binding upon and will inure to the benefit of the Parties and their respective permitted assignees or successors in interest, including those that may succeed by assignment, transfer or otherwise to the ownership of the assets necessary to the conduct of the business to which this Agreement relates. This Agreement may not be assigned or otherwise transferred by either Party without the prior written consent of the other Party; provided, however, that either Party may, without such consent, assign or otherwise transfer this Agreement, together with all of its rights and obligations hereunder, to any of its Affiliates, or (a) by Servier to a successor in interest in connection with the transfer or sale of all or substantially all of its business to which this Agreement relates (including by transfer or sale of all or any portion of Servier's assets, equity or business), or in the event of its merger or consolidation or similar business combination transaction, and (b) by Precision to a successor in interest (i) in connection with an assignment or transfer of all or substantially all of Precision's or any of its Affiliates' then-current business related to the Products collectively to a single or multiple assignee(s) or its/their Affiliates in a single transaction or series of related transactions (including by transfer or sale of all or any portion of Precision's assets, equity or business), or (ii) in the event of its merger, consolidation, Change of Control of Precision or similar business combination transaction. Any purported assignment in violation of the preceding sentences in this Section 8.1 shall be void. Any permitted assignee or successor shall assume and be bound by all obligations of its assignor or predecessor under this Agreement, including with respect to Precision, payment obligations under Sections 3.2 through 3.5 of this Agreement.

8.2. Headings; Rules of Construction. Headings are inserted for convenience and shall not affect the meaning or interpretation of this Agreement. Each Party agrees that this Agreement shall be interpreted without regard to any presumption or rule requiring construction against the Party causing this Agreement to be drafted. Except as otherwise explicitly specified to the contrary in this Agreement, (a) the words "hereof," "herein," "hereby," "hereunder" and words of similar import shall refer to this Agreement as a whole and not to any particular section or subsection of this Agreement and reference to a particular section of this Agreement shall include all subsections thereof, (b) references to a section, exhibit or schedule means a section of, or exhibit or schedule to, this Agreement unless such reference appears in amended text of the DCLA or refers specifically to a section of the DCLA, (c) definitions shall be equally applicable to both the singular and plural forms of the terms defined, and references to the masculine, feminine or neuter gender shall include each other gender, (d) the words "include," "includes" and "including" shall be deemed to be followed by the words "without limitation," (e) references to a rule, statute or regulation (including CPR rules and procedures) include all rules and regulations thereunder and any successor statute, rule or regulation, in each case as amended or otherwise modified from time to time, (f)

references to a particular Governmental Authority include any successor agency or body to such Governmental Authority and (g) references to "days" means calendar days, unless specified as Business Days.

8.3. Notices. Any notice or other communication given by one Party to the other Party under this Agreement must be in writing and shall be sufficient if (a) delivered personally or (b) sent by registered or certified mail, return receipt requested, reputable overnight business courier, email or fax, in each case properly addressed to the receiving Party as set forth below. The effective date of any notice or other communication given hereunder shall be the actual date of receipt by the receiving Party.

If to Precision:

Precision BioSciences, Inc.
302 East Pettigrew Street, Suite A-100
Durham, NC 27701
Facsimile: (480) 393-5553

Attention: Cindy Atwell, Senior Vice President, Business Development and Alliance Management

with a copy (which copy shall not constitute legal notice to Precision) to:

Smith, Anderson, Blount, Dorsett, Mitchell & Jernigan, LLP
150 Fayetteville Street, Suite 2300
Raleigh, NC 27601
Facsimile: (919) 821-6800
Attention: John R. Therien, Esq.

If to Servier:

Head of Alliance Management
Les Laboratoires Servier
Institut de Recherches Internationales Servier
50 rue Carnot
92284 Suresnes, France
Email: [***]
Attention: Alliance Management Director

with a copy (which copy shall not constitute legal notice to Servier) to:

Contracts Department Director
Les Laboratoires Servier
Institut de Recherches Internationales Servier
50 rue Carnot
92284 Suresnes, France
Email: [***]
Attention: Matthieu Guerineau

8.4. Dispute Resolution. In the event of a dispute arising out of or in connection with this Agreement, the Parties shall endeavor to solve the problem amicably and promptly by negotiation between Executive Officers of the respective Parties, in each case who have authority to settle the dispute, claim or controversy. If a Party provides written notice to the other Party regarding any such dispute and such dispute is not resolved through such negotiation procedures within [***] after receipt of such written notice by the other Party, any and all disputes arising out of or in connection with this Agreement shall be finally settled by confidential arbitration in accordance with the rules of arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with said rules. Arbitration proceedings shall be held in New York, New York, USA. The language shall be in English.

8.5. Governing Law. Any dispute, claim or controversy arising under or related to this Agreement, including the construction, validity and performance of this Agreement, shall be governed in all respects by the substantive laws of the state of New York, excluding its provisions regarding conflicts of law.

8.6. Rights in Bankruptcy. All rights, powers and remedies of the Non-Debtor Party provided herein are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity (including under the Bankruptcy Laws) in the event of the commencement of a case under the Bankruptcy Laws by or against the Debtor Party. The Non-Debtor Party, in addition to the rights, power and remedies expressly provided herein, shall be entitled to exercise all other such rights and powers and resort to all other such remedies as may now or hereafter exist at law or in equity (including under the Bankruptcy Laws) in such event.

8.7. Severability. Whenever possible, each term and provision of this Agreement shall be interpreted in such manner as to be valid and effective under applicable Laws, but, if any term or provision of this Agreement is held to be invalid or unenforceable under applicable Laws, such term or provision shall be invalid and ineffective only to the extent of such invalidity or unenforceability, without invalidating or making unenforceable the remainder of this Agreement. In the event of such invalidity or unenforceability, the Parties shall use reasonable efforts to seek and agree on an alternative valid and enforceable provision that preserves the original purpose and intent of the Agreement.

8.8. Independent Contractors. It is understood that the Parties are independent contractors and engage in the operation of their own respective businesses, and neither Party hereto is to be considered the agent or partner of the other Party for any purpose whatsoever. Neither Party has any authority to enter into any contracts or assume any obligations for the other Party or make any representations or warranties on behalf of the other Party.

8.9. Entire Agreement. This Agreement and the surviving provisions of the DCLA constitute the entire agreement between the Parties and shall cancel and supersede any and all prior and contemporaneous negotiations, correspondence, understandings and agreements, whether oral or written, between the Parties respecting the subject matter hereof, including the Confidentiality Agreement and that certain non-binding term sheet exchanged by the Parties prior to the Effective Date. To the extent there is a conflict

between this Agreement and the surviving provisions of the DCLA, this Agreement shall prevail.

8.10. Further Assurances. The Parties shall do and cause to be done, and shall cause their respective Affiliates to do and cause to be done, all such acts, matters, and things, and shall execute and deliver, and shall cause their respective Affiliates to execute and deliver, all such additional documents, instruments, conveyances, and assurances, and take such further actions, as may be required to carry out the provisions hereof and give effect to the transaction contemplated herein.

8.11. Amendment; Waiver. Any amendment or modification to this Agreement shall only be made in writing and shall only be valid when signed by an authorized representative of each Party. No term or provision of this Agreement, including the Parties' respective obligations, may be waived except by a writing signed by the Party against which such waiver is sought to be enforced.

8.12. Compliance with Laws. Each Party will comply with all applicable Laws in performing its obligations and exercising its rights hereunder.

8.13. Counterparts. This Agreement may be executed in more than one counterpart, each of which shall be deemed an original, but all of such counterparts taken together shall constitute one and the same agreement. This Agreement may be executed and delivered electronically or by facsimile and upon such delivery such electronic or facsimile signature will be deemed to have the same effect as if the original signature had been delivered to the other Party.

IN WITNESS WHEREOF, the Parties have caused this Program Purchase Agreement to be executed by their duly authorized representatives.

For Precision BioSciences, Inc.

By: /s/ Matthew Kane
Name: Matt KANE
Title: CEO

For Les Laboratoires Servier

By: /s/ Eric Falcand
Name: Eric FALCAND
Title: Proxy

For Institut de Recherches Internationales Servier

By: /s/ Claude Bertrand
Name: Claude BERTRAND
Title: Executive Vice President R&D

SCHEDULE 1 – REVERSION PROGRAM (Section 1.12(a), (b) and (c))

[***]

SCHEDULE 2 - WIRE TRANSFER INSTRUCTION

[***]

SCHEDULE 3 – APPROVED PARAGRAPHS AND QUOTATION

[***]

SCHEDULE 4 – ARBITRATION PROCEDURES FOR PROCEEDS ALLOCATION

[***]

Exhibit 10.2

EXECUTIVE EMPLOYMENT AGREEMENT

This Executive Employment Agreement (the "Agreement") is made and entered into as of this 26th day of April, 2021 (the "Effective Date"), by and between Precision BioSciences, Inc. (the "Company"), and Dr. Alan List ("Executive"). The Company and Executive are sometimes referred to in this Agreement individually as a "Party" and collectively as the "Parties."

BACKGROUND

The Company wishes to employ Executive on the terms set forth in this Agreement, and Executive wishes to accept such employment on the same terms.

NOW, THEREFORE, in consideration of the foregoing, of the mutual promises herein, and of other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending legally to be bound, hereby agree as follows:

1. EMPLOYMENT. As of the Effective Date, the Company hereby employs Executive and Executive hereby accepts employment as Chief Medical Officer of the Company upon the terms and conditions of this Agreement.

2. NATURE OF EMPLOYMENT/DUTIES. Executive shall serve as Chief Medical Officer of the Company and shall have such responsibilities and authority as the Company may designate from time to time consistent with Executive's title and position.

2.1 Executive shall perform all duties and exercise all authority in accordance with, and otherwise comply with, all Company policies, procedures, practices and directions.

2.2 Executive shall devote substantially all working time, best efforts, knowledge and experience to perform successfully Executive's duties and advance the Company's interests. During Executive's employment, Executive may, with the Board's consent (which shall not be unreasonably withheld), engage in other business activities for compensation (including board memberships), provided that, such activities do not present a conflict of interest nor violate the Restrictive Covenant Agreement (defined in Section 6), nor otherwise prohibit Executive from fulfilling Executive's obligations hereunder.

2.3 The parties have mutual interest in engaging in good faith discussions concerning a possible evolution of Executive's role at the Company in the future, either as an employee or advisor, with a focus on clinical development strategy.

3. COMPENSATION.

3.1 Base Salary. Executive's annual base salary for all services rendered shall be four hundred fifth-three thousand and 00/100 Dollars ($453,000) (less applicable taxes and withholdings) payable in accordance with the Company's payroll practices as they may exist from time to time ("Base Salary"). Base Salary may be reviewed and adjusted by the Company, at its discretion, in accordance with the Company's policies, procedures, and practices as they may exist

from time to time, provided that the Base Salary shall not be decreased unless the decrease is an across-the-board decrease for all senior management employees of the Company.

3.2 Business Expenses. Executive shall be reimbursed for reasonable and necessary expenses actually incurred by Executive in performing services under this Agreement in accordance with and subject to the terms and conditions of the applicable Company reimbursement policies, procedures, and practices as they may exist from time to time. All such reimbursements shall be made no later than the end of the calendar year following the year in which the expense was incurred.

3.3 Bonus. Executive may participate in any Company bonus plan the Company may adopt for senior management subject to the terms, conditions, and any eligibility requirements that may exist in such plan or plans. Executive's annual incentive compensation under such bonus plan (the "Annual Bonus") shall be targeted at forty percent (40%) of Executive's Base Salary (such target, as may be increased by the Board from time to time, the "Target Annual Bonus"). The Annual Bonus payable under the bonus plan shall be based on the achievement of performance goals to be determined by the Board. The payment of any Annual Bonus pursuant to the bonus plan shall be subject to Executive's continued employment with the Company through the date of payment.

3.4 Equity. Executive shall be eligible to participate in any equity compensation plan or similar program adopted by the Company when approved by the Board and, if applicable, the Company's shareholders, for executives at Executive's level. Executive will receive a stock option grant after joining the Company. The amount awarded, if any, to the Executive under any such plan shall be in the discretion of the Board or any committee administering such plan and shall be subject to the terms and conditions of any plan or program adopted or approved by the Board. Any such grants will be effective when made and shall be subject to terms and conditions to be imposed by the Board under the Company's plans, programs or applicable award agreement.

3.5 Benefits. Executive may participate in all medical, dental and disability insurance, 401(k), personal leave and other employee benefit plans and programs of the Company for which Executive is eligible, provided, however, that Executive's participation in benefit plans and programs is subject to the applicable terms, conditions and eligibility requirements of these plans and programs, some of which are within the plan administrator's discretion, as they may exist from time to time. The Company shall pay annual dues and expenses for Executive's membership and participation in such professional organizations as may be approved by the Board.

4. TERM OF EMPLOYMENT AND TERMINATION. The Company and Executive acknowledge that Executive's employment is and shall continue to be at-will, as defined under applicable law, and that Executive's employment with the Company may be terminated by either Party at any time for any or no reason (subject to the notice requirements of this Section 4). This "at-will" nature of Executive's employment shall remain unchanged during Executive's tenure as an employee and may not be changed, except in an express writing signed by Executive and a duly authorized officer of the Company. The term of this Agreement and Executive's employment hereunder shall commence on the Effective Date and continue until terminated as set forth in this Section 4. The date on which Executive's employment terminates, as determined by the Company, regardless of the reason, shall be referred to herein as the "Separation Date." Upon termination of

Executive's employment for any reason, Executive shall be deemed to have resigned from all offices and directorships, if any, then held with the Company or any of its subsidiaries.

4.1 Without Cause, Upon Notice. Either the Company or Executive may terminate Executive's employment and this Agreement without Cause at any time upon giving the other party thirty (30) days written notice.

4.2 For Cause. The Company may terminate Executive's employment and this Agreement immediately without notice at any time for "Cause," which shall mean the following:

4.2.1 Executive's material failure to perform his duties or to carryout the reasonable and lawful instructions of the Chief Executive Officer or the Board of Directors (other than any such failure resulting from incapacity due to physical or mental illness);

4.2.2 The Company concludes that Executive has, whether during or prior to his employment with the Company, engaged in dishonesty, illegal conduct, or gross misconduct, whether or not related to Executive's employment with the Company;

4.2.3 Executive's embezzlement, misappropriation, or fraud, whether or not related to the Executive's employment with the Company;

4.2.4 Executive is criminally charged, convicted, enters a plea, or agrees to any deferred judgment, deferred prosecution agreement or non-prosecution agreement, for any federal or state crime other than a traffic-related misdemeanor;

4.2.5 Executive is excluded, suspended, debarred, disqualified, indicted or otherwise criminally or civilly charged by any government entity with commission of the kinds of conduct for which a person may be excluded, suspended, debarred. or disqualified, under the Generic Drug Enforcement Act of 1992, as amended (21 USC § 335a, et seq.), section 1128 of the Social Security Act (42 USC § 1320a-7), or under any similar law or regulation of any state or country;

4.2.6 Executive's failure to cooperate with the Company in any investigation or formal proceeding;

4.2.7 Executive's material breach of any material obligation under this Agreement, the Restrictive Covenant Agreement (as defined in Section 6), or any other written agreement between the Executive and the Company; or

4.2.8 any material failure by Executive to comply with the Company's written policies or rules, including but not limited to the Company's conflict of interest policies or rules, as they may be in effect from time to time.

Provided, however, that prior to termination based on Sections 4.2.1, 4.2.6 or 4.2.7, Executive shall be given written notice of the facts allegedly constituting Cause and a ten (10) day opportunity to cure.

4.3 By Death or Disability. Executive's employment and this Agreement shall terminate upon Executive's Disability or death. For purposes of this Agreement, "Disability" shall mean Executive's inability, due to physical or mental incapacity, to perform the essential functions of Executive's job, with or without reasonable accommodation, for one hundred eighty (180) days out of any three hundred sixty-five (365) day period; provided however, in the event that the Company temporarily replaces the Executive, or transfers the Executive's duties or responsibilities to another individual on account of the Executive's inability to perform such duties due to a mental or physical incapacity which is, or is reasonably expected to become, a Disability, then the Executive's employment shall not be deemed terminated by the Company. Any question as to the existence of the Executive's Disability as to which the Executive and the Company cannot agree shall be determined in writing by a qualified independent physician mutually acceptable to the Executive and the Company. If the Executive and the Company cannot agree as to a qualified independent physician, each shall appoint such a physician and those two physicians shall select a third who shall make such determination in writing. The determination of Disability made in writing to the Company and the Executive shall be final and conclusive for all purposes of this Agreement. The Company shall give Executive written notice of termination for Disability and the termination shall be effective as of the date specified in such notice.

4.4 For Good Reason. Executive may terminate Executive's employment for "Good Reason," which shall mean the occurrence of any of the following, in each case without the Executive's written consent:

4.4.1 a material reduction in Executive's Base Salary other than a general reduction in Base Salary that affects all similarly situated executives;

4.4.2 an involuntary relocation of the Executive's principal place of employment by more than thirty five (35) miles; or

4.4.3 the Company's failure to obtain an agreement from any successor to the Company to assume and agree to perform this Agreement in the same manner and to the same extent that the Company would be required to perform if no succession had taken place, except where such assumption occurs by operation of law.

Executive cannot terminate Executive's employment for Good Reason unless Executive has provided written notice to the Company of the existence of the circumstances providing grounds for termination for Good Reason within thirty (30) days of the initial existence of such grounds and the Company has had at least thirty (30) days from the date on which such notice is provided to cure such circumstances. If the Executive does not terminate Executive's employment for Good Reason within sixty (60) days after the first occurrence of the applicable grounds, then the Executive will be deemed to have waived Executive's right to terminate for Good Reason with respect to such grounds.

5. COMPENSATION AND BENEFITS UPON TERMINATION. If Executive's employment terminates for any reason, Executive shall not be entitled to any payments, benefits, damages, award or compensation other than as provided in this Agreement or otherwise agreed to in writing by the Company or as provided by applicable law. Upon termination of Executive's

employment pursuant to any of the circumstances listed in Section 4, Executive (or Executive's estate) shall be entitled to receive the sum of: (i) the portion of Executive's Base Salary earned through the Separation Date, but not yet paid to Executive; (ii) any expense reimbursements owed to Executive pursuant to Section 3.2; and (iii) any amount accrued and arising from Executive's participation in, or benefits accrued under any employee benefit plans, programs or arrangements, which amounts shall be payable in accordance with the terms and conditions of such employee benefit plans, programs or arrangements (collectively, the "Accrued Obligations"). Except as otherwise expressly required by law (e.g., COBRA) or as specifically provided herein, all of Executive's rights to salary, severance, benefits, bonuses and other compensatory amounts hereunder (if any) shall cease upon the termination of Executive's employment hereunder. In the event that Executive's employment is terminated by the Company for any reason, Executive's sole and exclusive remedy shall be to receive the payments and benefits described in this Section 5.

5.1 By the Company for Cause or because of Executive's Death or Disability, or by Executive Without Cause, Upon Notice. If Executive's employment and this Agreement are terminated by the Company for Cause or because of Executive's death or Disability, or by Executive pursuant to Section 4.1 (Without Cause, Upon Notice), then the Company's obligation to compensate Executive ceases on the Separation Date except for the Accrued Obligations.

5.2 By the Company Without Cause or by Executive for Good Reason. If the Company terminates Executive's employment and this Agreement pursuant to Section 4.1 (Without Cause, Upon Notice) or Executive terminates Executive's employment and this Agreement pursuant to Section 4.4 (for Good Reason), subject to Executive's continued compliance with Executive's obligations under the Restrictive Covenant Agreement then the Company shall pay Executive the Accrued Obligations and subject to Section 5.5 (Required Release), Executive shall be entitled to the following:

5.2.1 pay Executive an amount equal to nine (9) months of Executive's then current monthly base salary (less applicable taxes and withholdings (the "Severance Period"), payable in substantially equal monthly installments on the same payroll schedule applicable to Executive immediately prior to Executive's separation from service and commencing on the first such payroll date on or following the date on which the release of claims required by Section 5.5 becomes effective and non-revocable, but not later than ninety (90) days following termination from employment; provided however that if the 90th day following Executive's termination from employment occurs in the year following the year in which Executive's termination occurs, then the payments shall commence no earlier than January 1 of such subsequent year and provided further that if such payments commence in such subsequent year, the first such payment shall be a lump sum in an amount equal to the payments that would have come due since Executive's separation from service, and

5.2.2 If Executive timely and properly elects health continuation coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985 ("COBRA"), during the Severance Period, the Company shall reimburse Executive for the difference between the monthly COBRA premium paid by the Executive and the monthly premium amount paid by Executive immediately prior to the date that Executive's employment terminated. Such reimbursement shall be paid to the Executive on or before the tenth (10th) day of the month

immediately following the month in which the Executive timely remits the premium payment, with such reimbursements to commence when the payments under Section 5.2.1 commence. Executive shall be eligible to receive such reimbursement until the earliest of: (i) the twelfth-month anniversary of the Separation Date; (ii) the date the Executive is no longer eligible to receive COBRA continuation coverage; and (iii) the date on which the Executive becomes eligible to receive substantially similar coverage from another employer or other source. Notwithstanding the foregoing, if the Company's making payments under this Section 5.2.2 would violate the nondiscrimination rules applicable to non-grandfathered plans under the Affordable Care Act (the "ACA"), or result in the imposition of penalties under the ACA and the related regulations and guidance promulgated thereunder), the parties agree to reform this Section 5.2.2 in a manner as is necessary to comply with the ACA. Executive shall provide the Company with notice of subsequent employment and comparable coverage within thirty (30) days of commencement of such comparable coverage.

5.3 Following a Change in Control, by the Company Without Cause or by Executive for Good Reason. If within three (3) month prior to or twelve (12) months following the occurrence of a Change in Control, as defined herein, either the Company terminates Executive's employment and this Agreement pursuant to Section 4.1 (Without Cause, Upon Notice) or Executive terminates Executive's employment and this Agreement pursuant to Section 4.4 (for Good Reason), then in lieu of any benefits under Section 5.2, and subject to Executive's continued compliance with Executive's obligations under the Restrictive Covenant Agreement, the Company shall pay Executive the Accrued Obligations and, subject to Section 5.5 (Required Release), Executive shall be entitled to the following:

5.3.1 The Company shall pay Executive an amount equal to twelve (12) months of Executive's then current monthly base salary (less applicable taxes and withholdings) (the "CIC Severance Period") plus one (1) times Executive's target bonus for the year during which the Separation Date occurs, payable in lump sum seventy-five (75) days following the Separation Date;

5.3.2 If Executive timely and properly elects health continuation coverage under COBRA, during the CIC Severance Period, the Company shall reimburse Executive for the difference between the monthly COBRA premium paid by the Executive and the monthly premium amount paid by Executive immediately prior to the date that Executive's employment terminated. Such reimbursement shall be paid to the Executive on or before the tenth (10th) day of the month immediately following the month in which Executive timely remits the premium payment, with such reimbursements to commence in the month following the month the release under Section 5.4 becomes effective and non-revocable. Executive shall be eligible to receive such reimbursement until the earliest of: (i) the twelfth-month anniversary of the Separation Date; (ii) the date the Executive is no longer eligible to receive COBRA continuation coverage; and (iii) the date on which the Executive becomes eligible to receive substantially similar coverage from another employer or other source. Notwithstanding the foregoing, if the Company's making payments under this Section 5.3.2 would violate the nondiscrimination rules applicable to non-grandfathered plans under the ACA, or result in the imposition of penalties under the ACA and the related regulations and guidance promulgated thereunder), the parties agree to reform this Section 5.3.2 in a manner as is necessary to comply with the ACA. Executive shall provide the

Company with notice of subsequent employment and comparable coverage within thirty (30) days of commencement of such comparable coverage; and

5.3.3 All unvested time-based equity grants shall vest in full as of the Separation Date, provided that such equity shall remain subject to the other terms and conditions of the applicable Company incentive award plan(s) and individual award agreement(s).

5.4 Definition of Change in Control.

5.4.1 **"**Change in Control" means and includes each of the following:

(a) A transaction or series of transactions (other than an offering of Common Stock to the general public through a registration statement filed with the Securities and Exchange Commission or a transaction or series of transactions that meets the requirements of clauses (i) and (ii) of subsection (c) below) whereby any "person" or related "group" of "persons" (as such terms are used in Sections 13(d) and 14(d)(2) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")) (other than the Company, any of its Subsidiaries, an employee benefit plan maintained by the Company or any of its Subsidiaries or a "person" that, prior to such transaction, directly or indirectly controls, is controlled by, or is under common control with, the Company) directly or indirectly acquires beneficial ownership (within the meaning of Rule 13d-3 under the Exchange Act) of securities of the Company possessing more than 50% of the total combined voting power of the Company's securities outstanding immediately after such acquisition; provided, however, that for purposes of this Agreement, "Subsidiary" means any entity (other than the Company), whether domestic or foreign, in an unbroken chain of entities beginning with the Company if each of the entities other than the last entity in the unbroken chain beneficially owns, at the time of the determination, securities or interests representing at least 50% of the total combined voting power of all classes of securities or interests in one of the other entities in such chain; or

(b) During any period of two consecutive years, individuals who, at the beginning of such period, constitute the Board of Directors (the "Board") together with any new director(s) of the Board (other than a director designated by a person who shall have entered into an agreement with the Company to effect a transaction described in subsections (a) or (c)) whose election by the Board or nomination for election by the Company's stockholders was approved by a vote of at least two-thirds of the directors then still in office who either were directors at the beginning of the two-year period or whose election or nomination for election was previously so approved, cease for any reason to constitute a majority thereof; or

(c) The consummation by the Company (whether directly involving the Company or indirectly involving the Company through one or more intermediaries) of (x) a merger, consolidation, reorganization, or business combination or (y) a sale or other disposition of all or substantially all of the Company's assets in any single transaction or series of related transactions or (z) the acquisition of assets or stock of another entity, in each case other than a transaction:

(i) which results in the Company's voting securities outstanding immediately before the transaction continuing to represent (either by remaining outstanding or by being converted into voting securities of the Company or the person that, as a result of the transaction, controls, directly or indirectly, the Company or owns, directly or indirectly, all or substantially all of the Company's assets or otherwise succeeds to the business of the Company (the Company or such person, the "Successor Entity")) directly or indirectly, at least a majority of the combined voting power of the Successor Entity's outstanding voting securities immediately after the transaction, and

(ii) after which no person or group beneficially owns voting securities representing 50% or more of the combined voting power of the Successor Entity; provided, however, that no person or group shall be treated for purposes of this clause (ii) as beneficially owning 50% or more of the combined voting power of the Successor Entity solely as a result of the voting power held in the Company prior to the consummation of the transaction.

5.4.2 Notwithstanding the foregoing, if a Change in Control constitutes a payment event under this Agreement that provides for the deferral of compensation that is subject to Section 409A of the Internal Revenue Code of 1986, as amended (the "Code"), and the regulations thereunder (collectively, "Section 409A"), to the extent required to avoid the imposition of additional taxes under Section 409A, the transaction or event described in subsection (a), (b) or (c) with respect to such payment (or portion thereof) shall only constitute a Change in Control for purposes of the payment timing if such transaction also constitutes a "change in control event," as defined in Treasury Regulation Section 1.409A-3(i)(5).

5.4.3 The Company shall have full and final authority, which shall be exercised in its discretion, to determine conclusively whether a Change in Control has occurred pursuant to the above definition, the date of the occurrence of such Change in Control and any incidental matters relating thereto; provided that any exercise of authority in conjunction with a determination of whether a Change in Control is a "change in control event" as defined in Treasury Regulation Section 1.409A-3(i)(5) shall be consistent with such regulation.

5.5 Required Release. Notwithstanding any provision of this Agreement to the contrary, the Company's obligation to provide the payments and reimbursements under Sections 5.2.1, 5.2.2, 5.3.1 and 5.3.2 is conditioned upon Executive's execution of a standard form of an enforceable release of claims and Executive's compliance with the Restrictive Covenant Agreement. If Executive chooses not to execute such a release or fails to comply with the Restrictive Covenant Agreement, then the Company's obligation to compensate Executive ceases on the Separation Date except as to amounts due at the time. The release of claims shall be provided to Executive within ten (10) days of Executive's separation from service and Executive must execute it within the time period specified in the release (which shall not be longer than forty-five (45) days from the date of receipt). Such release shall not be effective until any applicable revocation period has expired.

5.6 Benefits in Lieu of Other Severance. Executive is not entitled to receive any compensation or benefits upon Executive's termination except as: (i) set forth in this Agreement; (ii) otherwise required by law; or (iii) otherwise required by any employee benefit plan in which Executive participates. Moreover, the terms and conditions afforded Executive under

this Agreement are in lieu of any severance benefits to which Executive otherwise might be entitled pursuant to any severance plan, policy and practice of the Company. However, in the event Executive departs the Company, either upon Executive's termination or if employment is terminated by the Company pursuant to Section 4.1, Executive will be provided with the opportunity to review and comment upon the content of the press release, and the Company will consider such comments in good faith.

6. RESTRICTIVE COVENANTS. As a condition of employment, Executive will be obligated under the Proprietary Information, Inventions, Non-Competition and Non-Solicitation Agreement, executed simultaneously herewith (the "Restrictive Covenant Agreement"). Executive agrees to abide by the terms of the Restrictive Covenant Agreement, or any other subsequent agreement with the Company relating to proprietary information, inventions, intellectual property, non-competition or non-solicitation, the terms of which are hereby incorporated by reference into this Agreement. Executive acknowledges that the provisions of the Restrictive Covenant Agreement, or any subsequent similar agreement, will survive the termination of Executive's employment and/or the termination of this Agreement.

7. COMPANY PROPERTY. Upon the termination of Executive's employment or upon Company's earlier request, Executive shall: (i) deliver to the Company all records, memoranda, data, documents and other property of any description which refer or relate in any way to trade secrets or confidential information, including all copies thereof, which are in Executive's possession, custody or control; (ii) deliver to the Company all Company property (including, but not limited to, keys, credit cards, customer files, contracts, proposals, work in process, manuals, forms, computer-stored work in process and other computer data, research materials, other items of business information concerning any Company customer, or Company business or business methods, including all copies thereof) which is in Executive's possession, custody or control; (iii) bring all such records, files and other materials up to date before returning them; and (iv) fully cooperate with the Company in winding up Executive's work and transferring that work to other individuals designated by the Company.

8. CONSULTING AGREEMENT. Upon the Effective Date, the Consulting Agreement by and between the parties dated April 14, 2020 and as amended by its terms on August 31, 2020 (the "Consulting Agreement"), shall be terminated in all material respects and shall be of no further force or effect and this Agreement shall supersede the Consulting Agreement and neither the Company nor Executive shall have any further rights or obligations thereunder. For the avoidance of doubt, in entering into this Agreement, Employee acknowledges, agrees and represents that the Consulting Agreement has been terminated in its entirety; such termination is due to the Employee's voluntary termination of the Consulting Agreement pursuant to Section 10(C) of such agreement, with all notice obligations under Section 10(C) of the Consulting Agreement being deemed satisfied in full. Employee expressly acknowledges and agrees that the rights and obligations contained in each of Sections 4 ("Ownership of Inventions / Work Product"), and 8 ("Confidential Information") of the Consulting Agreement survives the termination of the Consulting Agreement and shall continue in effect pursuant to its terms. The stock options granted pursuant to the Consulting Agreement shall continue to vest in accordance with the terms and conditions to of the Company's plans, programs or applicable award agreement.

9. EMPLOYEE REPRESENTATION. Executive represents and warrants that Executive's employment and obligations under this Agreement will not (i) breach any duty or obligation Executive owes to another or (ii) violate any law, recognized ethics standard or recognized business custom.

10. AMENDMENTS; WAIVERS. This Agreement may not be modified, amended, or terminated except by an instrument in writing, signed by Executive and a duly authorized officer of Company. By an instrument in writing similarly executed, Executive or a duly authorized officer of the Company may waive compliance by the other Party with any specifically identified provision of this Agreement that such other Party was or is obligated to comply with or perform; *provided, however*, that such waiver shall not operate as a waiver of, or estoppel with respect to, any other or subsequent failure. No failure to exercise and no delay in exercising any right, remedy, or power hereunder will preclude any other or further exercise of any other right, remedy, or power provided herein or by law or in equity.

11. ENTIRE AGREEMENT. Except as expressly provided in this Agreement, this Agreement: (i) supersedes and cancels all other understandings and agreements, oral or written, with respect to Executive's employment with the Company; (ii) supersedes all other understandings and agreements, oral or written, between the parties with respect to the subject matter of this Agreement; and (iii) constitutes the sole agreement between the parties with respect to this subject matter. Each party acknowledges that: (i) no representations, inducements, promises or agreements, oral or written, have been made by any party or by anyone acting on behalf of any party, which are not embodied in this Agreement; and (ii) no agreement, statement or promise not contained in this Agreement shall be valid. No change or modification of this Agreement shall be valid or binding upon the parties unless such change or modification is in writing and is signed by the parties.

12. SEVERABILITY. If a court of competent jurisdiction holds that any provision or sub-part thereof contained in this Agreement is invalid, illegal, or unenforceable, that invalidity, illegality, or unenforceability shall not affect any other provision in this Agreement.

13. ASSIGNMENT AND SUCCESSORS. The Company may assign its rights and obligations under this Agreement to any of its affiliates or to any successor to all or substantially all of the business or the assets of the Company (by merger or otherwise), and may assign or encumber this Agreement and its rights hereunder as security for indebtedness of the Company and its affiliates. This Agreement shall be binding upon and inure to the benefit of the Company, Executive and their respective successors, assigns, personnel and legal representatives, executors, administrators, heirs, distributees, devisees, and legatees, as applicable. None of Executive's rights or obligations may be assigned or transferred by Executive, other than Executive's rights to payments hereunder, which may be transferred only by will or operation of law.

14. GOVERNING LAW. This Agreement shall be construed, interpreted, and governed in accordance with and by North Carolina law and the applicable provisions of federal law ("Applicable Federal Law"). Any and all claims, controversies, and causes of action arising out of or relating to this Agreement, whether sounding in contract, tort, or statute, shall be governed by the laws of the state of North Carolina, including its statutes of limitations, except for Applicable Federal Law, without giving effect to any North Carolina conflict-of-laws rule that

would result in the application of the laws of a different jurisdiction. Both Executive and the Company acknowledge and agree that the state or federal courts located in North Carolina have personal jurisdiction over them and over any dispute arising under this Agreement, and both Executive and the Company irrevocably consent to the jurisdiction of such courts.

15. **COUNTERPARTS.** This Agreement may be executed in counterparts, each of which shall be an original, with the same effect as if the signatures affixed thereto were upon the same instrument.

16. **NOTICES**. Any notice, request, claim, demand, document and other communication hereunder to any Party shall be effective upon receipt (or refusal of receipt) and shall be in writing and delivered personally or sent by facsimile or certified or registered mail, postage prepaid, as follows:

16.1 If to the Company, to the Chief Executive Officer of the Company at the Company's headquarters,

16.2 If to Executive, to the last address that the Company has in its personnel records for Executive, or

16.3 At any other address as any Party shall have specified by notice in writing to the other Party.

17. **SECTION 409A OF THE INTERNAL REVENUE CODE.** The parties intend that the provisions of this Agreement comply with Section 409A of the Internal Revenue Code of 1986, as amended (the "Code"), and the regulations thereunder (collectively, "Section 409A") and all provisions of this Agreement shall be construed in a manner consistent with the requirements for avoiding taxes or penalties under Section 409A. If any provision of this Agreement (or of any award of compensation, including equity compensation or benefits) would cause Executive to incur any additional tax or interest under Section 409A, the Company shall, upon the specific request of Executive, use its reasonable business efforts to in good faith reform such provision to comply with Code Section 409A; provided, that to the maximum extent practicable, the original intent and economic benefit to Executive and the Company of the applicable provision shall be maintained, and the Company shall have no obligation to make any changes that could create any additional economic cost or loss of benefit to the Company. The Company shall timely use its reasonable business efforts to amend any plans and programs in which Executive participates to bring it in compliance with Section 409A. Notwithstanding the foregoing, the Company shall have no liability with regard to any failure to comply with Section 409A so long as it has acted in good faith with regard to compliance therewith.

17.1 **Separation from Service.** A termination of employment shall not be deemed to have occurred for purposes of any provision of this Agreement providing for the payment of any amounts or benefits upon or following a termination of employment unless such termination also constitutes a "Separation from Service" within the meaning of Section 409A and, for purposes of any such provision of this Agreement, references to a "termination," "termination of employment," "separation from service" or like terms shall mean Separation from Service.

17.2 Separate Payments. Each installment payment required under this Agreement shall be considered a separate payment for purposes of Section 409A.

17.3 Delayed Distribution to Specified Employee. If the Company determines in accordance with Sections 409A and 416(i) of the Code and the regulations promulgated thereunder, in the Company's sole discretion, that Executive is a Specified Employee of the Company on the date Executive's employment with the Company terminates and that a delay in benefits provided under this Agreement is necessary to comply with Code Section 409A(A)(2)(B)(i), then any severance payments and any continuation of benefits or reimbursement of benefit costs provided by this Agreement, and not otherwise exempt from Section 409A, shall be delayed for a period of six (6) months following the date of termination of Executive's employment (the "409A Delay Period"). In such event, any severance payments and the cost of any continuation of benefits provided under this Agreement that would otherwise be due and payable to Executive during the 409A Delay Period shall be paid to Executive in a lump sum cash amount in the month following the end of the 409A Delay Period. For purposes of this Agreement, "Specified Employee" shall mean an employee who, on an Identification Date ("Identification Date" shall mean each December 31) is a specified employee as defined in Section 416(i) of the Code without regard to paragraph (5) thereof. If Executive is identified as a Specified Employee on an Identification Date, then Executive shall be considered a Specified Employee for purposes of this Agreement during the period beginning on the first April 1 following the Identification Date and ending on the following March 31.

17.4 Reimbursements. To the extent required by Section 409A, each reimbursement or in-kind benefit provided under this Agreement shall be provided in accordance with the following: (a) the amount of expenses eligible for reimbursement, or in-kind benefits provided, during each calendar year cannot affect the expenses eligible for reimbursement, or in-kind benefits to be provided, in any other calendar year; (b) any reimbursement of an eligible expense shall be paid to Executive on or before the last day of the calendar year following the calendar year in which the expense was incurred; and (c) any right to reimbursements or in-kind benefits under this Agreement shall not be subject to liquidation or exchange for another benefit.

18. PARACHUTE PAYMENTS. Notwithstanding any other provisions of this Agreement or any Company equity plan or agreement, in the event that any payment or benefit by the Company or otherwise to or for the benefit of Executive, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise (all such payments and benefits, including the payments and benefits under Section 5 hereof, being hereinafter referred to as the "Total Payments"), would be subject (in whole or in part) to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then the Total Payments shall be reduced (in the order provided in Section 16.1) to the minimum extent necessary to avoid the imposition of the Excise Tax on the Total Payments, but only if (i) the net amount of such Total Payments, as so reduced (and after subtracting the net amount of federal, state and local income and employment taxes on such reduced Total Payments and after taking into account the phase out of itemized deductions and personal exemptions attributable to such reduced Total Payments), is greater than or equal to (ii) the net amount of such Total Payments without such reduction (but after subtracting the net amount of federal, state and local income and employment taxes on such Total Payments and the amount of the Excise Tax to which Executive would be subject in respect of such

unreduced Total Payments and after taking into account the phase out of itemized deductions and personal exemptions attributable to such unreduced Total Payments).

18.1 **Order of Reduction**. The Total Payments shall be reduced in the following order: (i) reduction on a pro-rata basis of any cash severance payments that are exempt from Section 409A of the Code ("Section 409A"), (ii) reduction on a pro-rata basis of any non-cash severance payments or benefits that are exempt from Section 409A, (iii) reduction on a pro-rata basis of any other payments or benefits that are exempt from Section 409A, and (iv) reduction of any payments or benefits otherwise payable to Executive on a pro-rata basis or such other manner that complies with Section 409A; provided, in case of clauses (ii), (iii) and (iv), that reduction of any payments attributable to the acceleration of vesting of Company equity awards shall be first applied to Company equity awards that would otherwise vest last in time.

18.2 **Determinations.** All determinations regarding the application of this Section 17 shall be made by an accounting firm or consulting group with experience in performing calculations regarding the applicability of Section 280G of the Code and the Excise Tax selected by the Company (the "Independent Advisors"). For purposes of determinations, no portion of the Total Payments shall be taken into account which, in the opinion of the Independent Advisors, (i) does not constitute a "parachute payment" within the meaning of Section 280G(b)(2) of the Code (including by reason of Section 280G(b)(4)(A) of the Code) or (ii) constitutes reasonable compensation for services actually rendered, within the meaning of Section 280G(b)(4)(B) of the Code, in excess of the "base amount" (as defined in Section 280G(b)(3) of the Code) allocable to such reasonable compensation. The costs of obtaining such determination and all related fees and expenses (including related fees and expenses incurred in any later audit) shall be borne by the Company.

18.3 **Additional Reductions.** In the event it is later determined that a greater reduction in the Total Payments should have been made to implement the objective and intent of this Section 17, the excess amount shall be returned promptly by Executive to the Company.

[The remainder of this page is intentionally left blank.]

IN WITNESS WHEREOF, the parties have entered into this Agreement on the day and year first written above.

DR. ALAN LIST

/s/ Alan List, M.D.

PRECISION BIOSCIENCES, INC.

By: /s/ Matthew R. Kane

Title: CEO

Exhibit 10.3

Certain information marked as [***] has been excluded from this exhibit because it is both not material and is the type that the registrant treats as private or confidential

CONSULTING AGREEMENT

This CONSULTING AGREEMENT ("**Agreement**") is made by and between Precision BioSciences,Inc., a Delaware corporation having a place of business at 302 East Pettigrew Street, Dibrell Building,Suite A-100, Durham, NC 27701 ("**Company**"), and Dr. Chris Heery, an individual having an address at[***] as of April 23, 2021 (the "**Effective Date**").

The Company desires to retain the services of the Independent Contractor, and the Independent Contractor desires to perform certain services for the Company. In consideration of the mutual covenants and promises contained herein and other good and valuable consideration, the receipt andsufficiency of which is hereby acknowledged by the parties hereto, the parties agree as follows:

1. ENGAGEMENT OF SERVICES.
The Company hereby engages the Independent Contractor, and the Independent Contractor accepts the engagement to provide the Company with such consulting, advisory and related services as may reasonably be requested by the Company from time to time ("**Services**"). All Services will be performed by Independent Contractor in a diligent and professional manner.

2. COMPENSATION.
In consideration of the Services to be performed by the Independent Contractor under this Agreement,the Company will pay the Independent Contractor the flat rate of $600 per hour, but not to exceed a maximum under this Agreement of $35,000, for time spent on mutually accepted Services. The Independent Contractor shall submit written, signed reports of the time spent performing Services, itemizing in reasonable detail the dates on which Services were performed, the number of hours spent on such dates and a brief description of the Services rendered. The Company shall pay the Independent Contractor the amounts due on a monthly basis pursuant to submitted reports, within 30 days of receipt thereof. Independent Contractor will also be entitled to continued vesting through July 23, 2021 of any outstanding unvested stock options held by the Independent Contractor as of April 23, 2021 and the right to exercise any vested stock options (after giving effect to the foregoing continued vesting) held by the Independent Contractor as of July 23, 2021 shall be extended until April 23, 2022, subject in all events to earlier termination in connection with a corporate transaction or event in accordance with the terms of such stock options.

3. EXPENSES.
The Independent Contractor will be reimbursed for ordinary and necessary expenses incurred by theIndependent Contractor in the performance of Services hereunder that have been expressly approvedin advance by the Company ("**Expenses**"), provided that the Independent Contractor has furnished such documentation for authorized expenses as the Company may reasonably request. The Independent Contractor shall submit written documentation and receipts where available, itemizing the dates on which expenses are incurred. The Company shall pay the Independent Contractor the amounts due pursuant to submitted reports, within 30 days receipt thereof.

4. OWNERSHIP OF INVENTIONS / WORK PRODUCT.
A. The Independent Contractor agrees that any inventions, discoveries, improvements, processes, technology, know-how, software, designs, documentation, results, data, compilations of data and samples (whether or not patentable and whether or not reduced to practice) arising or made directly or

indirectly by or on behalf of the Independent Contractor (solely or jointly with others) in the courseof performance of Services under this Agreement or that are based on, derived from, or related to information received from the Company, and any and all patents and other intellectual property rightstherein or issuing thereon (collectively, "**Inventions**"), shall be the property of the Company. The Independent Contractor further agrees that all works of authorship which are made by or on behalf of the Independent Contractor (solely or jointly with others) in the course of performance of Services under this Agreement and which are protectable by copyright are "works made for hire," as that termis defined in the 1976 Copyright Act as amended (title 17 of the *United States Code*) ("**Works of Authorship**"; and together with Inventions, "**Work Product**"). The Independent Contractor agreesto assign and hereby unconditionally and irrevocably assigns to the Company all right, title and interest in and to the Inventions and, to the extent such right, title and interest does not vest in the Company as "works made for hire", all right, title and interest in and to the Works of Authorship. Inorder to permit the Company to claim rights to which it may be entitled under this Section 4 or applicable laws, and to ensure that there is no conflict with any business or activities of the Company,all inventions, discoveries, improvements, processes, technology, know-how, software, designs, documentation, results, data, compilations of data and samples (whether or not patentable and whetheror not reduced to practice) and all works of authorship which the Independent Contractor may conceive or make (solely or jointly with others) during the term of this Agreement and during the sixmonths following the termination of this Agreement and related to the Services performed under thisAgreement shall be promptly disclosed to the Company in confidence.

B. Whenever requested by the Company, the Independent Contractor shall execute patent applications and copyright registrations and such other documents considered necessary by the Company or its counsel to apply for and obtain letters patent and copyright registrations in the UnitedStates, foreign countries, or both, as the Company may deem advisable, or to otherwise protect the Work Product for the benefit of the Company coming within the Company's rights as provided for inSection 4.A. The Independent Contractor shall also make such assignments and execute such other instruments as may be necessary to convey to the Company the ownership and exclusive right in andto the Work Product and all related intellectual property rights. The Company shall bear all of the documented expenses incurred by the Independent Contractor in connection with the obtaining of such rights. The Independent Contractor further agrees to cooperate to the extent and in the manner requested by the Company in the prosecution or defense of any such patent or copyright or other intellectual property claims or any litigation or other proceeding involving any Work Product in anycountry of the world, but all time and documented expenses thereof shall be paid by the Company. The foregoing covenant and the rights of the Company under this Section 4 include, without limitation, any improvements of properties, rights, systems, inventions, works of authorship and the like presently held by the Company or any affiliate thereof.

C. If Independent Contractor has any rights in or to any Work Product that cannot be assigned to Company under applicable law, then Independent Contractor agrees to grant and hereby unconditionally and irrevocably grants to Company an exclusive, irrevocable, perpetual, worldwide,fully paid and royalty-free license, with rights to sublicense through multiple levels of sublicenses, tomake, have made, sell, offer for sale, use, import, reproduce, create derivative works of, distribute, publicly perform and publicly display and otherwise exploit by all means now known or later developed, such rights without any duty to report or provide any accounting for such exploitation, and agrees, at Company's request and expense, to consent to and join in any action to enforce such rights. If Independent Contractor has any rights in or to Work Product that cannot be assigned or licensed to Company under applicable law, then Independent Contractor agrees to waive and hereby

unconditionally and irrevocably waives the enforcement of such rights, and all claims and causes of action of any kind against Company and its affiliates, licensees, successors and assigns with respect to such rights.

D. In the event that any deliverable under this Agreement incorporates or requires for its use intellectual property rights of the Independent Contractor, the Independent Contractor agrees to grantand hereby grants to Company a worldwide, perpetual, irrevocable, fully paid, royalty-free, non- exclusive license, with rights to sublicense through multiple levels of sublicenses, under suchintellectual property rights to use and otherwise exploit all such deliverables for any purpose.

5. REPRESENTATIONS AND WARRANTIES.
The Independent Contractor represents and warrants that the Independent Contractor has the right andunrestricted ability to enter this Agreement and to perform all of its obligations contained herein. Without limiting the foregoing, the Independent Contractor represents and warrants that it has the right to assign the entire right, title and interest in and to the Work Product to the Company pursuantto Section 4.

6. NO DEBARMENT.
The Independent Contractor represents and warrants that neither Independent Contractor nor any of its employees nor any other person engaged by it to perform the Services:

A. Is presently debarred, disqualified or convicted for a crime for which a person or entity can be debarred under the Generic Drug Enforcement Act of 1992 (21USC335a) or under any similar law or regulation of any country (collectively, the "**Acts**");

B. Is presently indicted or otherwise criminally or civilly charged by any government entity withcommission of the kinds of conduct for which a person or entity can be debarred ordisqualified under the Acts;

C. Will employ or otherwise engage any individual who has been (i) debarred or disqualified or (ii) convicted of a crime for which a person or entity can be debarred or disqualified under theActs, in any capacity in connection with the Services.

The Independent Contractor shall immediately notify the Company if it becomes aware of any circumstances that may cause the foregoing representation and warranty to become untrue, includingif the Independent Contractor or any such other person comes under investigation by any governmental agency for debarment or disqualification or is debarred or disqualified.

7. INDEPENDENT CONTRACTOR RELATIONSHIP.
The Independent Contractor's relationship with the Company is that of an independent contractor, and nothing in this Agreement is intended to, or should be construed to, create a partnership, agency,joint venture or employment relationship. The Independent Contractor shall not be entitled to any ofthe benefits that the Company may make available to its employees, including, but not limited to, group health or life insurance, profit sharing, or retirement benefits, except as expressly stated in thisAgreement. The Independent Contractor is not authorized to make any representation, contract, or commitment on behalf of the Company unless specifically requested or authorized in writing to do soby an executive officer of the Company. The Independent Contractor is solely responsible for, and will file, on a timely basis, all tax returns and payments required to be filed with, or made to, any federal, state, or local tax authority with respect to the performance of services and receipt of fees

under this Agreement. The Independent Contractor is solely responsible for, and must maintain adequate records of, expenses incurred in the course of performing services under this Agreement. The Company will not withhold for the payment of any social security, federal, state, or any other employee payroll taxes payable with respect to the Independent Contractor. The Company will, as applicable, regularly report amounts paid to the Independent Contractor by filing Form 1099-MISC with the Internal Revenue Service as required by law.

8. CONFIDENTIAL INFORMATION.

A. The Independent Contractor agrees to hold all Confidential Information in strict confidence, not to disclose Confidential Information to any third parties, and shall use the Confidential Information solely for performing the Independent Contractor's obligations under this Agreement. "ConfidentialInformation" as used in this Agreement shall mean all information disclosed by the Company to the Independent Contractor that is not generally known in the Company's trade or industry and shall include, without limitation, (a) concepts and ideas relating to the research, development, use, and distribution of technologies and products made or developed by the Company; (b) trade secrets, drawings, inventions, know-how, methods, materials, grants, grant proposals, collaborative work, partners, employees, and software programs; (c) information regarding plans for research, development, new service offerings or products, marketing and selling, business plans, business forecasts, budgets and unpublished financial statements, licenses and distribution arrangements, prices and costs, suppliers and customers; (d) existence of any business discussions, negotiations or agreements; (e) any information regarding the skills and compensation of employees, contractors or other agents of the Company or its subsidiaries or affiliates; and (f) all Work Product. Confidential Information also includes proprietary or confidential information of any third party that may disclosesuch information to the Company or the Independent Contractor in the course of the Company's business. The Independent Contractor's obligations set forth in this Section shall not apply with respect to any portion of the Confidential Information that the Independent Contractor can document (i) was in the public domain at the time it was communicated to the Independent Contractor by the Company; (ii) entered the public domain through no fault of the Independent Contractor, subsequentto the time it was communicated to the Independent Contractor by the Company; (iii) was in the Independent Contractor's possession free of any obligation of confidence at the time it was communicated to the Independent Contractor by the Company; or (iv) was rightfully communicatedto the Independent Contractor by a third party free of any obligation of confidence subsequent to thetime it was communicated to the Independent Contractor by the Company. In addition, the Independent Contractor may disclose the Company's Confidential Information in response to a validorder by a court or other governmental body, or as otherwise required by law, provided that the Independent Contractor provides reasonable notice to the Company such that the Company can pursue its rights in seeking protection of such information. All Confidential Information furnished to the Independent Contractor by the Company is the sole and exclusive property of the Company or itssuppliers or customers. Upon request by the Company at any time, the Independent Contractor agreesto promptly deliver to the Company the originals and any copies of such Confidential Information.

B. The Independent Contractor represents that its performance of the terms of the Agreement does not and will not conflict with the terms of any agreement to keep in confidence proprietaryinformation and trade secrets acquired in confidence or in trust prior to his/her advisory relationshipwith the Company or to refrain from competing, directly or indirectly, with the business of any otherperson or entity. The Independent Contractor will not disclose to the Company, or induce the Company to use, any confidential or proprietary information or material belonging to any third party.

C. The Independent Contractor recognizes that Company may have confidential information from third parties which is subject to a duty on Company's part to maintain such information in confidenceand, in some cases to use it only for certain purposes. Independent Contractor agrees that they owe Company and such third party, both during the term of this Agreement and thereafter, a duty to holdall such confidential information in strict confidence and not to disclose it to any person, firm, or entity or use such information for the benefit of anyone other than Company or such third party.

9. NO CONFLICT OF INTEREST.

The Independent Contractor represents that he/she has the right and authority to enter into this Agreement and by doing such will not be in breach of any existing agreements. The Independent Contractor will not accept work, enter into a contract, or accept an obligation from any third party that is inconsistent with the Independent Contractor's obligations under this Agreement.

10.TERM AND TERMINATION.

A. TERM: The term of this Agreement shall commence as of the Effective Date and end on July 31, 2021, unless this Agreement is earlier terminated as provided below. The Independent Contractor's obligation of confidentiality with respect to any particular item of Confidential Information obtained under this Agreement shall continue, notwithstanding the termination or expiration of this Agreement, until the Confidential Information falls into one of the categories listed in clauses (ii) and (iv) of Section 8.A.

B. TERMINATION BY COMPANY: The Company may terminate this Agreement at any time, with or without cause, and without prejudice to any right or remedy it may have due to any failure of the Independent Contractor to perform its obligations under this Agreement, including failure to perform Services in a diligent and professional manner, upon thirty (30) days written notice of termination to the Independent Contractor. In the event that the Companyterminates the Independent Contractor's services hereunder, the Company shall (i) promptly pay theIndependent Contractor all monies due through the date of notice of termination and (ii) pay the Independent Contractor for non-cancellable Expenses incurred hereunder prior to the date of notice of termination. Unless the Company terminates the Agreement due to failure of the Independent Contractor to perform its obligations under this Agreement, including failure to perform Services in a diligent and professional manner, termination of the Independent Contractor's services hereunder will not affect the extension of the right of the Independent Contractor to exercise any vested stock options held by the Independent Contractor thirty (30) days after written notice of termination until April 23, 2022.

C. TERMINATION BY INDEPENDENT CONTRACTOR: The Independent Contractor may terminate this Agreement at any time, with or without cause, upon thirty (30) days written noticeof termination to the Company.

D. EFFECT OF TERMINATION; SURVIVAL: Upon notice of termination pursuant to Section 10.B or 10.C, unless otherwise requested in writing by the Company with respect to the thirty (30) day termination notice period, the Independent Contractor shall stop all work under thisAgreement and incur no further expenses hereunder. If the Independent Contractor performsadditional Services or incurs additional Expenses at the Company's written request in such thirty (30)day period, the Company shall pay the Independent Contractor for such Services and reimburse the Independent Contractor for such Expenses in accordance with Sections 2 and 3. The rights and obligations contained in Sections 4 ("Ownership of Inventions / Work Product"), 5 ("Representationsand Warranties"), 8 ("Confidential Information"), 9 ("No Conflict of Interest"), 11 ("Indemnification"), 14 ("Governing Law") 17 ("Injunctive Relief for Breach") and 18 ("Release") shall survive anytermination or expiration of this Agreement.

11.INDEMNIFICATION
The Independent Contractor shall indemnify and hold the Company harmless from all claims, losses,damages, expenses, fees (including reasonable attorneys' fees), costs and judgments that may be asserted against or incurred by the Company that result from the acts or omissions of the IndependentContractor and its agents.

The Company shall indemnify and hold the Independent Contractor harmless from all claims, losses, damages, expenses, fees (including reasonable attorneys' fees), costs and judgments that may be asserted against or incurred by the Independent Contractor that result from the acts or omissions of the Company and its agents. (As explained in Paragraph 7, the Independent Contractor is not an agent of the Company.)

12.SUCCESSORS AND ASSIGNS.
The Independent Contractor may not subcontract or otherwise delegate its obligations under this Agreement or assign this Agreement without the Company's prior written consent, and any attempt without such consent shall be null and void. This Agreement will be for the benefit of the Company'ssuccessors and assigns, and subject to the foregoing sentence, will be binding on the Independent Contractor's assignees.

13.NOTICES.
Any notice required or permitted by this Agreement shall be in writing and shall be delivered as follows with notice deemed given as indicated: (i) by personal delivery when delivered personally; (ii) by overnight courier upon written verification of receipt; (iii) by telecopy or facsimile transmission upon acknowledgment of receipt of electronic transmission; or (iv) by certified or registered mail, return receipt requested, upon verification of receipt. Notice shall be sent to the addresses set forth below or such other address as either party may specify in writing.

14.GOVERNING LAW.
This Agreement shall be governed by and constructed in accordance with the laws of the State of North Carolina, excluding that body of law known as choice of law, and shall be binding upon the parties hereto in the United States and worldwide. The state courts located in Wake County, North Carolina, or the federal district court for the Eastern District of North Carolina located in Raleigh, North Carolina, shall have exclusive jurisdiction to adjudicate any dispute arising out of thisAgreement. The parties consent to personal jurisdiction of such courts and service of process being affected by registered mail sent to the address set forth at the beginning of this Agreement.

15.SEVERABILITY.
Should any provisions of this Agreement be held by a court of law to be illegal, invalid orunenforceable, the legality, validity and enforceability of the remaining provisions of this Agreementshall not be affected or impaired thereby.

16.WAIVER.
The waiver by the Company of a breach of any provision of this Agreement by the Independent Contractor shall not operate or be construed as a waiver of any other or subsequent breach by the Independent Contractor.

17.INJUNCTIVE RELIEF FOR BREACH.
The Independent Contractor's obligations under this Agreement are of a unique character that gives them particular value; breach or any threatened breach of any of such obligations will result in

irreparable and continuing damage to the Company for which there will be no adequate remedy at law; and, in the event of such breach, the Company will be entitled to injunctive relief and/or a decree for specific performance, and such other and further relief as may be proper (including monetary damages if appropriate).

18.RELEASE.
In consideration of the benefits conferred by this Agreement, EMPLOYEE (ON BEHALF OF EMPLOYEE AND EMPLOYEE'S ASSIGNS, HEIRS, AND OTHER REPRESENTATIVES) RELEASES THE COMPANY, ITS PREDECESSORS, SUCCESSORS, AND ASSIGNS AND ITS AND/OR THEIR PAST, PRESENT, AND FUTURE OWNERS, PARENTS, SUBSIDIARIES, AFFILIATES, PREDECESSORS, SUCCESSORS, ASSIGNS, OFFICERS, DIRECTORS, EMPLOYEES, EMPLOYEE BENEFIT PLANS (TOGETHER WITH ALL PLAN ADMINISTRATORS, TRUSTEES, FIDUCIARIES, AND INSURERS), AND AGENTS ("RELEASEES") FROM ALL CLAIMS AND WAIVES ALL RIGHTS, KNOWN OR UNKNOWN, EMPLOYEE MAY HAVE OR CLAIM TO HAVE RELATING TO EMPLOYEE'S EMPLOYMENT WITH THE COMPANY, ITS PREDECESSORS, SUBSIDIARIES, OR AFFILIATES OR EMPLOYEE'S SEPARATION THEREFROM arising before the execution of this Agreement. The release of claims set forth in this paragraph does not apply to: (i) claims for workers' compensation benefits or unemployment benefits filed with the applicable state agencies, or to (ii) claims for vested retirement benefits, or (iii) claims based on acts that take place after this Agreement is signed.

19.ENTIRE AGREEMENT.
This Agreement constitutes the entire agreement between the parties relating to this subject matter and supersedes all prior or contemporaneous oral or written agreements concerning such subject matter. The terms of this Agreement will govern all services undertaken by the Independent Contractor for the Company. This Agreement may only be changed by mutual agreement of authorized representatives of the parties in writing. This Agreement and any related amendments may be executed and delivered by facsimile or PDF and in one or more counterparts, each of which shall be deemed an original and all of which together shall constitute one document.

[*signature page follows on the next page*]

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first writtenabove.

Precision BioSciences, Inc.

By: /s/ Matthew R. Kane
Title: CEO

Independent Contractor

By: /s/ Christopher Heery, M.D.
Title: Independent Contractor

Exhibit 10.4

PRECISION BIOSCIENCES, INC.

NON-EMPLOYEE DIRECTOR COMPENSATION PROGRAM

Non-employee members of the board of directors (the "***Board***") of Precision BioSciences, Inc. (the "***Company***") shall receive cash and equity compensation as set forth in this Non-Employee Director Compensation Program, as amended from time to time (this "***Program***"). The cash and equity compensation described in this Program shall be paid or be made, as applicable, automatically and without further action of the Board, to each member of the Board who is not an employee of the Company or any parent or subsidiary of the Company (each, a "***Non-Employee Director***") who is entitled to receive such cash or equity compensation, unless such Non-Employee Director declines the receipt of such cash or equity compensation by written notice to the Company. This Program shall remain in effect until it is revised or rescinded by further action of the Board. This Program may be amended, modified or terminated by the Board at any time in its sole discretion. The terms and conditions of this Program shall supersede any prior cash and/or equity compensation arrangements for service as a member of the Board between the Company and any of its Non-Employee Directors, except for equity compensation previously granted to a Non-Employee Director.

CASH COMPENSATION

The schedule of annual retainers (the "***Annual Retainers***") for the Non-Employee Directors is as follows:

Position	**Amount**
Base Board Fee	$40,000
Chair of Audit Committee	$15,000
Chair of Compensation Committee	$12,250
Chair of Science & Technology Committee	$12,250
Chair of Nominating and Corporate Governance Committee	$8,250
Member of Audit Committee (non-Chair)	$7,500
Member of Compensation Committee (non-Chair)	$6,000
Member of Science & Technology Committee (non-Chair)	$6,000
Member of Nominating and Corporate Governance Committee (non-Chair)	$4,500

For the avoidance of doubt, the Annual Retainers in the table above are additive and a Non-Employee Director shall be eligible to earn an Annual Retainer for each position in which he or she serves. The Annual Retainers shall be earned on a quarterly basis based on a calendar quarter and shall be paid in cash by the Company in arrears not later than the fifteenth day following the end of each calendar quarter. In the event a Non-Employee Director does not serve as a Non-Employee Director, or in the applicable position, for an entire calendar quarter, the retainer paid to such Non-Employee Director shall be prorated for the portion of such calendar quarter actually served as a Non-Employee Director, or in such position, as applicable.

EQUITY COMPENSATION

Each Non-Employee Director shall be granted options to purchase the Company's common stock (each, an "***Option***") having an aggregate Grant Date Fair Value (as defined below) as set forth in the following table, with any partial shares that result being rounded down to the nearest whole share. Each Option shall be granted under and subject to the terms and provisions of the Company's 2019 Incentive Award Plan or any other applicable Company equity incentive plan then-maintained by the Company (the "***Equity Plan***") and shall be subject to an award agreement, including attached exhibits, in substantially the form previously approved by the Board. "***Grant Date Fair Value***" shall mean, with respect to an Option, the per share fair value of the Option determined as of the Option's date of grant using the Black-Scholes option pricing model that the Company most recently used in preparing its (audited or unaudited) consolidated financial statements that have been filed with the Securities Exchange Commission ("***Financial Statements***") and using as inputs into such model (i) the Fair Market Value of a share of the Company's common stock on the Option's date of grant and (ii) such other assumptions as were reported by the Company in the Financial Statements for the most recent period covered by the Financial Statements (and if any such assumptions were reported as a range of values, using the arithmetic mean of the reported values).

Option	Grant Date Fair Value
Initial Option	$350,000
Subsequent Option	$175,000

A.Initial Options. Each Non-Employee Director who is initially elected or appointed to the Board shall receive the Initial Option on the date of such initial election or appointment. No Non-Employee Director shall be granted more than one Initial Option.

B.Subsequent Options. A Non-Employee Director who (i) has been serving as a Non-Employee Director on the Board for at least six months as of the date of any annual meeting of the Company's stockholders and (ii) will continue to serve as a Non-Employee Director immediately following such meeting, shall be automatically granted a Subsequent Option on the date of such annual meeting. For the avoidance of doubt, a Non-Employee

Director elected for the first time to the Board at an annual meeting of the Company's stockholders shall only receive an Initial Award in connection with such election, and shall not receive any Subsequent Award on the date of such meeting as well.

C. Termination of Employment of Employee Directors. Members of the Board who are employees of the Company or any parent or subsidiary of the Company who subsequently terminate their employment with the Company and any parent or subsidiary of the Company and remain on the Board will not receive an Initial Option, but to the extent that they are otherwise entitled, will receive, after termination of employment with the Company and any parent or subsidiary of the Company, Subsequent Options.

D. Terms of Options Granted to Non-Employee Directors.

1. *Exercise Price*. The per-share exercise price of each Option granted to a Non-Employee Director shall equal the Fair Market Value (as defined in the Equity Plan) of a share of the Company's common stock on the date the Option is granted.

2.*Vesting*.

a.Initial Options. Each Initial Option shall vest and become exercisable in thirty-six (36) substantially equal monthly installments following the date of grant, such that the Initial Option shall be fully vested on the third anniversary of the date of grant, subject to the Non-Employee Director continuing in service as a Non-Employee Director through each such vesting date.

b.*Subsequent Options*. Each Subsequent Option shall vest and become exercisable on the earlier of the first anniversary of the date of grant or the day immediately prior to the date of the next annual meeting of the Company's stockholders occurring after the date of grant, in either case, subject to the Non-Employee Director continuing in service as a Non-Employee Director through such vesting date.

c.*Forfeiture of Options*. Unless the Board otherwise determines, any portion of an Initial Option or Subsequent Option which is unvested or unexercisable at the time of a Non-Employee Director's termination of service on the Board as a Non-Employee Director shall be immediately forfeited upon such termination of service and shall not thereafter become vested and exercisable. All of a Non-Employee Director's Initial Options and Subsequent Options shall vest in full immediately prior to the occurrence of a Change in Control (as defined in the Equity Plan), to the extent outstanding at such time.

3. *Term*. The maximum term of each Option granted to a Non-Employee Director hereunder shall be ten (10) years from the date the Option is granted.

Notwithstanding anything in this Program to the contrary, the sum of any cash compensation, or other compensation, and the value (determined as of the grant date in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718, or any successor thereto) of Options granted to a Non-Employee Director as compensation for services as a Non-Employee Director during any fiscal year of the Company may not exceed $750,000 (the "***NED Limit***"). The NED Limit shall be applied to reduce compensation in the following order: (A)

reduction in any Initial Option granted during such year; (B) reduction in any Subsequent Option granted during such year; (C) reduction on a pro-rata basis of any cash or other compensation, payments or benefits that are exempt from Section 409A of the Internal Revenue Code of 1986, as amended ("***Section 409A***") and (D) reduction of any cash or other compensation, payments or benefits otherwise payable to the Non-Employee Director on a pro-rata basis or such other manner that complies with Section 409A. The Board may make exceptions to the NED Limit in extraordinary circumstances, as the Board may determine in its discretion, provided that the Non-Employee Director receiving such additional compensation may not participate in the decision to award such compensation or in other contemporaneous compensation decisions involving Non-Employee Directors.

* * * * *

Exhibit 10.5

FOURTH AMENDMENT TO LEASE

THIS FOURTH AMENDMENT TO LEASE (this "***Amendment***") is made and entered into as of the _4__ day of May, 2021 (the "***Effective Date***"), by and between **DURHAM TW ALEXANDER, LLC**, a Delaware limited liability company ("***Landlord***"), and **PRECISION BIOSCIENCES, INC.**, a Delaware corporation (formerly a North Carolina corporation) ("***Tenant***").

STATEMENT OF PURPOSE

WHEREAS, Landlord and Tenant entered into that certain Lease dated October 2, 2018 ("***Initial Lease***"), as amended by that certain First Amendment to Lease dated December 23, 2019 (***"First Amendment"***), as further amended by that certain Second Amendment to Lease dated March 13, 2020 (***"Second Amendment***"), and as further amended by that certain Third Amendment to Lease dated June 15, 2020 (***"Third Amendment***") (as amended, the "***Existing Lease***"), for certain premises containing approximately 33,828 rentable square feet on the first (1st) floor (the "***Premises***") located in the building known as Biopoint Innovation Labs located at 20 TW Alexander Drive, Research Triangle Park, North Carolina 27709 (the "***Building***"), as more particularly described in the Lease.

WHEREAS, Landlord and Tenant desire to amend the terms of the Existing Lease: (i) to extend the date by which Tenant must utilize the Tenant Improvements Allowance, as defined in the First Amendment, and (ii) to modify certain other terms of the Existing Lease. For purposes hereof, the Lease as amended by this Amendment is referred to as the "***Lease***." All capitalized terms not otherwise defined herein shall have the meanings set forth in the Existing Lease.

NOW, THEREFORE, in consideration of the statement of purpose, the mutual covenants contained herein and other valuable consideration, the receipt of which is hereby acknowledged, the parties hereto agree as follows:

1. **Recitals**. The recitals shall form a part of this Amendment.

2. **Extension of the Tenant Improvements Allowance Disbursement Deadline**. Due to various delays in the performance of the Tenant Improvements, as defined in the First Amendment, Landlord and Tenant hereby agree that the deadline for Tenant to request disbursements from the Tenant Improvement Allowance under Section 2.2 of Exhibit C of the First Amendment shall be extended until December 30, 2021. For purposes of clarity, Landlord also hereby acknowledges and agrees that Tenant's delayed occupancy of the Premises and construction timeline does not constitute abandonment under Section 19.1.3 of the Lease.

3. **Counterparts/Signatures**. This Amendment may be executed in counterparts. All executed counterparts shall constitute one agreement, and each counterpart shall be deemed an original. The parties hereby acknowledge and agree that electronic signatures, facsimile signatures or signatures transmitted by electronic mail in so-called "pdf" format shall be legal and binding and shall have the same full force and effect as if an original of this Amendment had been delivered. Landlord and Tenant (i) intend to be bound by the signatures (whether original, faxed or electronic) on any document sent by facsimile or electronic mail, (ii) are aware that the other

party will rely on such signatures, and (iii) hereby waive any defenses to the enforcement of the terms of this Amendment based on the foregoing forms of signature.

4. **Miscellaneous**. This Amendment shall become effective only upon full execution and delivery of this Amendment by Landlord and Tenant. This Amendment contains the parties' entire agreement regarding the subject matter covered by this Amendment, and supersedes all prior correspondence, negotiations, and agreements, if any, whether oral or written, between the parties concerning such subject matter. There are no contemporaneous oral agreements, and there are no representations or warranties between the parties not contained in this Amendment. This Amendment shall be construed and enforced in accordance with the laws of the State of North Carolina. Except as modified by this Amendment, the terms and provisions of the Lease shall remain in full force and effect, and the Lease, as modified by this Amendment, shall be binding upon and shall inure to the benefit of the parties hereto, their successors and permitted assigns.

[***Signature Page Follows***]

[***The remainder of this page has been intentionally left blank***]

LANDLORD AND TENANT enter into this Amendment as of the Effective Date above.

LANDLORD:

DURHAM TW ALEXANDER, LLC,
a Delaware limited liability company

By: /s/ Adam Sichol

Name: Adam Sichol

Title: Authorized Signatory

Date: May 11_____, 2021

TENANT:

PRECISION BIOSCIENCES, INC.,
a Delaware corporation

By: /s/ Sinu Bhandaru

Name: Sinu Bhandaru

Title: Vice President Operations & IT

Exhibit 31.1

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

I, Matthew Kane, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended March 31, 2021 of Precision BioSciences, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: May 13, 2021

By: /s/ Matthew Kane

Matthew Kane
President, Chief Executive Officer and Director
(principal executive officer)

Exhibit 31.2

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

I, John Alexander Kelly, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended March 31, 2021 of Precision BioSciences, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: May 13, 2021

By: /s/ John Alexander Kelly
John Alexander Kelly
Interim Chief Financial Officer
(principal financial officer)

Exhibit 32.1

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

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

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

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

Date: May 13, 2021

By: /s/ Matthew Kane

Matthew Kane
President, Chief Executive Officer and Director
(principal executive officer)

Exhibit 32.2

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

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

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

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

Date: May 13, 2021

By: /s/ John Alexander Kelly

John Alexander Kelly
Interim Chief Financial Officer
(principal financial officer)