UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2022

or

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

For the transition period from _____ to _____

Commission File Number: 001-39376

Poseida Therapeutics, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**47-2846548**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
9390 Towne Centre Drive, Suite 200, San Diego, California	**92121**
(Address of Principal Executive Offices)	**(Zip Code)**

(858) 779-3100

(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	PSTX	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, a 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 August 8, 2022, the registrant had 85,775,587 shares of common stock, $0.0001 par value per share, outstanding.

POSEIDA THERAPEUTICS, INC.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q including statements regarding our future results of operations or financial condition, business strategy, plans and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements because they contain words such as “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will” or “would” or the negative of these words or other similar terms or expressions. These forward-looking statements include, but are not limited to, statements concerning the following:

- our expectations regarding the timing, scope and results of our development activities, including our ongoing and planned clinical trials;
- the timing of and plans for regulatory filings;
- our plans to obtain and maintain regulatory approvals of our product candidates in any of the indications for which we plan to develop them, and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- the potential benefits of our product candidates and technologies;
- our expectations regarding the use of our platform technologies to generate novel product candidates;
- the market opportunities for our product candidates and our ability to maximize those opportunities;
- our business strategies and goals;
- estimates of our expenses, capital requirements, any future revenue, and need for additional financing;
- our expectations regarding manufacturing capabilities and plans;
- the performance of our third-party suppliers and manufacturers;
- our ability to attract and/or retain new and existing collaborators with development, regulatory, manufacturing and commercialization expertise and our expectations regarding the potential benefits to be derived from such collaborations;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our platform technologies and product candidates and our ability to operate our business without infringing on the intellectual property rights of others;
- our expectations regarding developments and projections relating to our competitors, competing therapies that are or become available, and our industry;
- our expectations regarding the impact of the COVID-19 pandemic and the Russia-Ukraine conflict on our business and operations, anticipated timelines, our industry and the economy;
- future changes in or impact of law and regulations in the United States and foreign countries; and
- the sufficiency of our existing cash, cash equivalents and short-term investments to fund our operations.

We have based these forward-looking statements on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, strategy, short- and long-term business operations and objectives and financial needs.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in the section titled “Risk Factors” and elsewhere in this Quarterly Report on Form 10-Q. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Quarterly Report on Form 10-Q may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, advancements, discoveries, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, except as required by law, neither we nor any other person assumes responsibility for the accuracy and completeness of the

forward-looking statements. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Quarterly Report on Form 10-Q to conform these statements to actual results or to changes in our expectations.

Unless the context otherwise indicates, references in this Quarterly Report on Form 10-Q to the terms “Poseida”, “the Company,” “we,” “our” and “us” refer to Poseida Therapeutics, Inc. and its subsidiaries.

We regularly make material business and financial information available to our investors using our investor relations website (https://investors.poseida.com). We therefore encourage investors and others interested in Poseida to review the information that we make available on our website, in addition to following our filings with the Securities and Exchange Commission, or the SEC, press releases and conference calls.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

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

	June 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 62,963	$ 206,325
Short-term investments	79,594	—
Accounts receivable	232	—
Prepaid expenses and other current assets	5,330	7,548
Total current assets	148,119	213,873
Property and equipment, net	22,756	22,050
Operating lease right-of-use assets	27,981	26,177
Intangible assets	1,320	1,320
Goodwill	4,228	4,228
Other long-term assets	1,051	1,661
Total assets	$ 205,455	$ 269,309
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,661	$ 8,961
Accrued expenses and other liabilities	28,699	23,540
Operating lease liabilities, current	6,686	6,337
Deferred revenue, current	1,047	4,497
Total current liabilities	40,093	43,335
Operating lease liabilities, non-current	26,803	25,504
Term debt	58,065	29,357
Deferred CIRM grant liability	3,992	3,992
Deferred revenue, noncurrent	8,811	9,265
Deferred tax liability	55	55
Other long-term liabilities	1,836	1,590
Total liabilities	139,655	113,098
Commitments and Contingencies (Note 11)		
Stockholders' equity:		
Common stock, $0.0001 par value: 250,000,000 shares authorized at June 30, 2022 and December 31, 2021; 62,728,726 and 62,523,596 shares issued and outstanding as of June 30, 2022 and December 31, 2021, respectively	6	6
Additional paid-in capital	573,878	563,064
Accumulated other comprehensive loss	(132)	—
Accumulated deficit	(507,952)	(406,859)
Total stockholders' equity	65,800	156,211
Total liabilities and stockholders' equity	$ 205,455	$ 269,309

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenues:				
Collaboration revenue	$ 2,700	$ —	$ 4,135	$ —
Total revenue	2,700	—	4,135	—
Operating expenses:				
Research and development	35,008	36,008	83,858	65,103
General and administrative	9,237	8,871	18,782	17,240
Total operating expenses	44,245	44,879	102,640	82,343
Loss from operations	(41,545)	(44,879)	(98,505)	(82,343)
Other income (expense):				
Interest expense	(1,543)	(843)	(2,620)	(1,681)
Other income, net	52	17	32	5
Net loss before income tax	(43,036)	(45,705)	(101,093)	(84,019)
Income tax expense	—	—	—	—
Net loss	$ (43,036)	$ (45,705)	$ (101,093)	$ (84,019)
Other comprehensive expense:				
Unrealized loss on short-term investments	(132)	(14)	(132)	(4)
Comprehensive loss	$ (43,168)	$ (45,719)	$ (101,225)	$ (84,023)
Net loss per share, basic and diluted	$ (0.69)	$ (0.74)	$ (1.61)	$ (1.35)
Weighted-average number of shares outstanding, basic and diluted	62,713,363	62,150,961	62,635,074	62,066,498

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

POSEIDA THERAPEUTICS, INC.
Condensed Consolidated Statements of Changes in Stockholders' Equity
(In thousands, except share amounts)
(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at January 1, 2022	62,523,596	$ 6	$ 563,064	$ —	$ (406,859)	$ 156,211
Issuance of common stock under employee stock compensation plans	181,130	—	681	—	—	681
Stock-based compensation expense	—	—	4,867	—	—	4,867
Net loss	—	—	—	—	(58,057)	(58,057)
Balance at March 31, 2022	**62,704,726**	**$ 6**	**$ 568,612**	**$ —**	**$ (464,916)**	**$ 103,702**
Issuance of common stock under employee stock compensation plans	24,000	—	32	—	—	32
Stock-based compensation expense	—	—	5,234	—	—	5,234
Unrealized loss on available-for-sale investments	—	—	—	(132)	—	(132)
Net loss	—	—	—	—	(43,036)	(43,036)
Balance at June 30, 2022	**62,728,726**	**$ 6**	**$ 573,878**	**$ (132)**	**$ (507,952)**	**$ 65,800**

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at January 1, 2021	61,860,897	$ 6	$ 543,842	$ 5	$ (281,885)	$ 261,968
Issuance of common stock under employee stock compensation plans	265,839	—	360	—	—	360
Stock-based compensation expense	—	—	3,462	—	—	3,462
Unrealized gain on available-for-sale investments	—	—	—	10	—	10
Net loss	—	—	—	—	(38,314)	(38,314)
Balance at March 31, 2021	**62,126,736**	**$ 6**	**$ 547,664**	**$ 15**	**$ (320,199)**	**$ 227,486**
Issuance of common stock under employee stock compensation plans	39,431	—	67	—	—	67
Stock-based compensation expense	—	—	4,742	—	—	4,742
Unrealized loss on available-for-sale investments	—	—	—	(14)	—	(14)
Net loss	—	—	—	—	(45,705)	(45,705)
Balance at June 30, 2021	**62,166,167**	**$ 6**	**$ 552,473**	**$ 1**	**$ (365,904)**	**$ 186,576**

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

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

	Six Months Ended June 30,	
	2022	2021
Operating Activities:		
Net loss	$ (101,093)	$ (84,019)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	2,467	2,200
Deferred revenue	(3,903)	—
Non-cash loss on contract termination	5,687	—
Loss on disposal of property and equipment	205	5
Stock-based compensation	10,101	8,204
Accretion of discount on issued term debt	405	332
Accretion of investment discount, net	(97)	114
Changes in operating assets and liabilities:		
Accounts receivable	(232)	—
Prepaid expenses and other current assets	1,017	1,733
Operating lease right-of-use assets	2,262	1,817
Other long-term assets	610	(208)
Accounts payable	(5,859)	3,727
Accrued expenses and other liabilities	(205)	(2,694)
Operating lease liabilities	(2,418)	(1,355)
Net cash used in operating activities	(91,053)	(70,144)
Investing Activities:		
Purchases of property and equipment	(1,961)	(2,056)
Purchases of short-term investments	(79,611)	—
Proceeds from maturities of short-term investments	—	187,500
Net cash provided by (used in) investing activities	(81,572)	185,444
Financing Activities:		
Net proceeds from issuance of common stock under employee stock compensation plans	713	427
Payment of debt issuance costs	(1,450)	—
Proceeds from term debt	30,000	—
Net cash provided by financing activities	29,263	427
Net increase (decrease) in cash and cash equivalents	(143,362)	115,727
Cash and cash equivalents at beginning of period	206,325	83,966
Cash and cash equivalents at end of period	$ 62,963	$ 199,693
Non-cash operating, investing and financing activities:		
Purchases of property and equipment in accounts payable and accrued liabilities	$ 1,429	$ 109
Supplemental disclosure of cash flow information:		
Interest paid	$ 1,996	$ 1,356

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Note 1. Nature of Business and Basis of Presentation

Nature of Operations

Poseida Therapeutics, Inc. (the "Company" or "Poseida") is a clinical-stage biopharmaceutical company dedicated to utilizing its proprietary genetic engineering platform technologies to create next generation cell and gene therapeutics with the capacity to cure. The Company has discovered and is developing a broad portfolio of product candidates in a variety of indications based on its core proprietary platforms, including the Company's non-viral piggyBac DNA Delivery System, Cas-CLOVER Site-specific Gene Editing System and nanoparticle- and AAV-based gene delivery technologies.

The Company is subject to risks and uncertainties common to development-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts will require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities. Even if the Company's therapeutic development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales.

Liquidity and Capital Resources

The Company has experienced net losses and negative cash flows from operations since its inception and has relied on its ability to fund its operations primarily through equity and debt financings and collaborations. For the six months ended June 30, 2022, the Company incurred a net loss of $101.1 million and negative cash flows from operations of $91.1 million. The Company expects to continue to incur net losses and negative cash flows from operations for at least the next several years. As of June 30, 2022, the Company had an accumulated deficit of $508.0 million.

In July 2022, the Company entered into a collaboration and license agreement (the "Roche Collaboration Agreement") with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (collectively, "Roche"), pursuant to which, among other things, the Company will grant to Roche (i) an exclusive, worldwide license under certain Company intellectual property to develop, manufacture and commercialize allogeneic CAR-T cell therapy products from each of the Company's existing P-BCMA-ALLO1 and P-CD19CD20-ALLO1 programs, and (ii) an exclusive option to acquire an exclusive, worldwide license under certain Company intellectual property to develop, manufacture and commercialize allogenic CAR-T cell therapy products from each of the Company's existing P-BCMACD19-ALLO1 program and P-CD70-ALLO1 programs. Under the Roche Collaboration Agreement, subject to regulatory clearance, Roche is obligated to make an upfront payment to the Company of $110.0 million and the Company could also receive up to $110.0 million in near-term fees and milestone and other payments, and all of which has not yet been received.

Additionally, on August 8, 2022, the Company completed the sale of an aggregate of 23,000,000 shares of its common stock in an underwritten public offering, at a price of $3.50 per share, including 3,000,000 shares sold pursuant to the full exercise of the underwriters' option to purchase additional shares. The net proceeds to the Company from the offering were approximately $75.3 million after deducting underwriting discounts and commissions and estimated offering expenses payable by the Company.

The Company expects that its cash, cash equivalents and short-term investments as of June 30, 2022 of $142.6 million, in combination with the upfront payment of $110.0 million to be received pursuant to the Roche Collaboration Agreement and the net proceeds from the underwritten public offering of approximately $75.3 million, will be sufficient to fund its operations for at least the next twelve months from the date of issuance of these condensed consolidated financial statements. The combination of the upfront payment from Roche and the underwritten public offering have alleviated the previously disclosed substantial doubt about the Company ability to continue as a going concern. In the long term, the Company will need additional financing to support its continuing operations and pursue its business strategy. Until such time as the Company can generate significant revenue from product sales, if ever, it expects to finance its operations through a combination of equity offerings, debt financings, collaborations, strategic alliances, and licensing arrangements. The Company may be unable to raise additional funds or enter into such other agreements when needed on favorable terms or at all. The inability to raise capital as and when needed would have a negative impact on the Company's financial condition and its ability to pursue its business strategy. The Company will need to generate significant revenue to achieve profitability, and it may never do so.

Basis of Presentation and Consolidation

The accompanying condensed consolidated financial statements reflect the Company's financial position, results of operations and cash flows, in conformity with generally accepted accounting principles in the United States of America ("GAAP"), for interim

financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. The accompanying condensed consolidated financial statements include the accounts of Poseida Therapeutics, Inc. and its wholly owned subsidiaries. All intercompany transactions and balances have been eliminated. These unaudited condensed consolidated financial statements reflect all adjustments that are, in the opinion of management, necessary to fairly state the financial position and the results of its operations and cash flows for interim periods presented. Interim-period results are not necessarily indicative of results of operations or cash flows for a full year or any subsequent interim period. The accompanying condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2021, as filed with the Securities and Exchange Commission ("SEC") on March 10, 2022 from which the Company derived its condensed consolidated balance sheet as of December 31, 2021.

Risk and Uncertainties

In March 2020, the World Health Organization made the assessment that a novel strain of coronavirus, SARS-CoV-2, a novel strain of coronavirus, commonly referred to as COVID-19 had become a global pandemic. The impact of this pandemic has been and may continue to be extensive in many aspects of society, which has resulted in and may continue to result in significant disruptions to the global economy, as well as businesses and capital markets around the world.

Impacts to the Company's business, some of which the Company has experienced to date, include, but are not limited to, temporary closures of its facilities or those of its vendors, disruptions or restrictions on its employees' ability to travel, disruptions to or delays in ongoing laboratory experiments, preclinical studies, clinical trials, third-party manufacturing supply and other operations, the diversion of healthcare resources away from the conduct of clinical trials to focus on pandemic concerns, interruptions or delays in the operations of the U.S. Food and Drug Administration ("FDA") or other regulatory authorities, and the Company's ability to raise capital and conduct business development activities.

Russia's invasion of Ukraine and the retaliatory measures that have been taken, or could be taken in the future, by the United States, NATO, and other countries have created global security concerns that could result in a regional conflict and otherwise have a lasting impact on regional and global economies, any or all of which could disrupt the Company's supply chain and adversely affect its ability to conduct ongoing and future clinical trials of the Company's product candidates. The extent to which the ongoing conflict ultimately impacts the Company's business is highly uncertain and cannot be predicted with confidence at this time.

Note 2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires the Company to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. On an ongoing basis, the Company evaluates its estimates, which include, but are not limited to, estimates related to revenue, accrued expenses, research and development expenses, stock-based compensation expense and deferred tax valuation allowances. The Company bases its estimates on historical experience and other market-specific or relevant assumptions that it believes to be reasonable under the circumstances. Actual results may differ from those estimates or assumptions.

Fair Value Measurements

Certain financial instruments are required to be recorded at fair value. Other financial instruments, like cash are recorded at cost, which approximates fair value. Cash equivalents and short-term investments are comprised of available-for-sale securities, which are carried at fair value. Additionally, carrying amounts of accounts receivable, accounts payable and accrued liabilities approximate fair value because of the short maturity of those instruments. The carrying value of the Company's term debt approximates its fair value due to its variable interest rate, which approximates a market interest rate.

Concentration of Business Risk

The Company operates in one reportable business segment and has one customer. The Company relies, and expects to continue to rely, on a small number of vendors to manufacture supplies and materials for its development programs. These programs could be adversely affected by a significant interruption in these manufacturing services.

Leases

The Company accounts for leases in accordance with Accounting Standards Codification Topic 842, *Leases*, ("ASC 842"). The Company determines if an arrangement is a lease at contract inception. A lease exists when a contract conveys the right to control the use of identified property, plant, or equipment for a period of time in exchange for consideration. The definition of a lease embodies

two conditions: (1) there is an identified asset in the contract that is land or a depreciable asset (i.e., property, plant, and equipment), and (2) the Company has the right to control the use of the identified asset.

Operating leases where the Company is the lessee are included in operating lease right-of-use ("ROU") assets, operating lease liabilities, current and operating lease liabilities, non-current on its condensed consolidated balance sheets. The lease liabilities are initially and subsequently measured at the present value of the unpaid lease payments at the lease commencement date.

ASC 842 requires a lessee to discount its unpaid lease payments using the interest rate implicit in the lease or, if that rate cannot be readily determined, its incremental borrowing rate. The rates implicit in the Company's leases are not known, therefore, the incremental borrowing rate is used based on the information available at commencement date in determining the present value of lease payments. The Company's incremental borrowing rate for a lease is the rate of interest it would have to pay on a collateralized basis to borrow an amount equal to the lease payments under similar terms.

The lease term for all of the Company's leases includes the noncancelable period of the lease. Where the Company's lease term is impacted by options to extend or terminate the lease, when it is reasonably certain that it will exercise such option, then the lease payments are included in the measurement of the lease asset or liability.

The Company has elected not to recognize ROU assets and lease liabilities for all short-term leases that have a lease term of 12 months or less. The Company recognizes the lease payments associated with its short-term leases as an expense on a straight-line basis over the lease term. There are no variable lease payments associated with these leases. Additionally, the Company has elected to account for the lease and non-lease components together as a single lease component for its real estate asset class.

Revenue Recognition

The Company's revenues to date have been generated primarily through collaboration and license agreements. The Company's collaboration and license agreements may contain multiple elements including intellectual property licenses and research, and development services. Consideration the Company receives under these arrangements may include upfront payments, research and development funding, cost reimbursements, research, development, regulatory and commercial milestone payments, and royalty payments.

The Company applies Accounting Standard Codification Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), issued by the Financial Accounting Standards Board ("FASB") to account for its contracts with customers. Under ASC 606, revenue is recognized when a customer obtains control of promised goods or services. The amount of revenue recognized reflects the consideration that the Company expects to be entitled to receive in exchange for these services and excludes sales incentives and amounts collected on behalf of third parties. The Company analyzes the nature of these performance obligations in the context of individual collaboration and license agreements in order to assess the distinct performance obligations. The Company evaluates its contracts with customers for proper classification in the consolidated statements of operations based on the nature of the underlying activity. Transactions with customers recorded in the Company's consolidated statements of operations are recorded on either a gross or net basis, depending on the characteristics of the collaborative relationship.

To determine revenue recognition for arrangements within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that it will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer.

Accounts Receivable and Allowance for Credit Losses

Accounts receivable primarily consist of amounts due from customers for services and payments due based on contractual terms. Accounts receivable are recorded when the right to consideration becomes unconditional. For research and development services, the Company generally bills its customers monthly or quarterly as the services are performed. Payment terms on invoiced amounts are typically 30 - 60 days. The Company recognizes estimated allowance for credit losses based on an assessment of a customer's ability to pay, credit quality of the customer, age of receivable balances and current economic conditions. As of June 30, 2022 and December 31, 2021, the Company recorded no allowance for credit losses.

Emerging Growth Company Status

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it (i) is no longer an emerging growth company or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, these condensed consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

Recently Adopted Accounting Pronouncements

In May 2021, the FASB issued ASU 2021-04, *Earnings Per Share (Topic 260), Debt-Modifications and Extinguishments (Subtopic 470-50), Compensation- Stock Compensation (Topic 718), and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40)* which provides guidance on modifications or exchanges of a freestanding equity-classified written call option that is not within the scope of another Topic. An entity should treat a modification of the terms or conditions or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange as an exchange of the original instrument for a new instrument ASU 2021-04 also provides further guidance on measuring the effect of a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange. ASU 2021-04 also provides guidance on the recognition of the effect of a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange on the basis of the substance of the transaction, in the same manner as if cash had been paid as consideration. The Company adopted ASU 2021-04 on January 1, 2022. The adoption of this standard had no impact on the Company's condensed consolidated financial statements and disclosures.

Recently Issued Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, *Measurement of Credit Losses on Financial Instruments*, which established ASC 326, *Financial Instruments - Credit Losses*. This ASU, along with subsequent amendments, improves financial reporting by requiring timely recording of credit losses on loans and other financial instruments held by financial institutions and other organizations. ASU 2016-13 requires the measurement of all expected credit losses for financial assets held at the reporting date based on historical experience, current conditions and reasonable and supportable forecasts. This guidance will become effective for the Company beginning January 1, 2023, with early adoption permitted. The Company is currently evaluating the potential impact ASU 2016-13 may have on its financial position and results of operations upon adoption but does not expect the adoption will have a material impact on the Company's consolidated financial statements and disclosures.

Note 3. Composition of Certain Balance Sheet Components

Property and equipment, net

Property and equipment, net consisted of the following (in thousands):

	June 30, 2022	December 31, 2021
Laboratory equipment	$ 16,993	$ 14,192
Leasehold improvements	14,010	13,910
Computer equipment and software	2,235	2,137
Furniture, fixtures and other	999	948
Total property and equipment	34,237	31,187
Less: Accumulated depreciation and amortization	(11,481)	(9,137)
Total property and equipment, net	$ 22,756	$ 22,050

Depreciation and amortization expense associated with property and equipment was $1.3 million and $2.5 million for the three and six months ended June 30, 2022, respectively and $1.1 million and $2.2 million for the three and six months ended June 30, 2021, respectively.

Accrued expenses and other liabilities

Accrued expenses and other liabilities consisted of the following (in thousands):

	June 30, 2022	December 31, 2021
Contract research services	$ 14,439	$ 12,292
Accrued loss on contract termination	4,493	—
Payroll and related expense	6,001	8,760
Other	3,766	2,488
Total accrued expenses and other liabilities	$ 28,699	$ 23,540

The accrued loss on a contract termination represents a loss resulting from an early termination of the Company's contract with one of its autologous contract manufacturers during the six months ended June 30, 2022, consisting of future contractual payment obligations.

Note 4. Financial Instruments

The following table summarizes the amortized cost and fair value of securities available-for-sale (in thousands):

	Amortized Cost/Cost	Unrealized Gains	Unrealized Losses	Fair Value
June 30, 2022:				
Money market fund	$ 31,626	$ —	$ —	$ 31,626
U.S. government agency securities and treasuries	89,722	—	(132)	$ 89,590
Total	$ 121,348	$ —	$ (132)	$ 121,216
December 31, 2021:				
Money market fund	$ 176,102	$ —	$ —	$ 176,102
Total	$ 176,102	$ —	$ —	$ 176,102

The Company reviews its investment portfolio to identify and evaluate investments that have an indication of possible other-than-temporary impairment. Factors considered in determining whether a loss is other-than-temporary include the length of time and extent to which fair value has been less than the cost basis, the financial condition and near-term prospects of the investee, and the Company's intent and ability to hold the investment for a period of time sufficient to allow for any anticipated recovery in market value. The Company does not intend to sell any investments prior to recovery of their amortized cost basis for any investments in an unrealized loss position.

Note 5. Fair Value Measurement

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants as of the measurement date. Applicable accounting guidance provides an established hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs that market participants would use in valuing the asset or liability and are developed based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the factors that market participants would use in valuing the asset or liability. There are three levels of inputs that may be used to measure fair value:

- Level 1 — Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities
- Level 2 — Significant other observable inputs other than Level 1 prices such as quoted prices in markets that are not active, or inputs that are observable, either directly or indirectly, for substantially the full term of the asset or liability
- Level 3 — Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity)

The Company classifies its money market funds and U.S. treasury securities, which are valued based on quoted market prices in active markets with no valuation adjustment, as Level 1 assets within the fair value hierarchy.

The following table summarizes the Company's valuation hierarchy for its financial assets and liabilities measured at fair value on a recurring basis (in thousands):

	Level 1	Level 2	Level 3
June 30, 2022:			
Assets:			
Money market funds and U.S. government agency treasuries(1)	$ 41,622	$ —	$ —
Short-term investments	79,594	—	—
Total	$ 121,216	$ —	$ —
December 31, 2021:			
Assets:			
Money market funds(1)	$ 176,102	$ —	$ —
Total	$ 176,102	$ —	$ —

(1) Included in cash and cash equivalents in the accompanying condensed consolidated balance sheets.

Note 6. Collaborations and License Agreement with Takeda

In October 2021, the Company entered into a collaboration and license agreement (the "Takeda Collaboration Agreement") with Takeda Pharmaceuticals USA, Inc. ("Takeda"), pursuant to which the Company granted to Takeda a worldwide exclusive license under the Company's certain platform technologies including piggyBac, Cas-CLOVER, biodegradable DNA and RNA nanoparticle delivery technology and other proprietary genetic engineering platforms to research, develop, manufacture and commercialize gene therapy products for certain indications, including Hemophilia A. The parties are collaborating to initially develop up to six *in vivo* gene therapy programs and Takeda also has an option to add two additional programs to the collaboration. The Company is obligated to perform research activities to the extent requested by Takeda up to the candidate selection stage, after which Takeda is obligated to assume responsibility for further development, manufacturing and commercialization of each program.

Under the Takeda Collaboration Agreement, the Company received an upfront payment of $45.0 million, of which $5.0 million represents prepaid research funding. Takeda is obligated to provide funding for all collaboration program development costs; provided that the Company is obligated to perform certain platform development activities at its own cost. Under the Takeda Collaboration Agreement, the Company is eligible to receive preclinical milestone payments that could potentially exceed $82.5 million in the aggregate if preclinical milestones for all six programs are achieved. The Company is also eligible to receive future clinical development, regulatory and commercial milestone payments of $435.0 million in the aggregate per target, with a total potential deal value over the course of the collaboration of up to $2.7 billion, if milestones for all six programs are achieved and up to $3.6 billion if the milestones related to the two optional programs are also achieved. The Company is entitled to receive tiered royalty payments on net sales in the mid-single to low double digits, subject to certain standard reductions and offsets. Royalties will be payable, on a product-by-product and country-by-country basis, until the latest of the expiration of the licensed patents covering such product in such country, ten years from first commercial sale of such product in such country, or expiration of regulatory exclusivity for such product in such country.

The promised goods and services under the Takeda Collaboration Agreement were accounted for as following separate performance obligations: (i) development and commercialization licenses for initial two indications, (ii) separate material rights associated with four additional licenses Takeda has an option to acquire individually, (iii) platform technology enhancement services, and (iv) research and development services.

The Company recognizes revenue from platform technology enhancement services based on the amount of incurred development expenses reimbursed by the customer as a percentage of total expected reimbursable expenses associated with the contract. As of June 30, 2022, all future potential milestone payments were excluded from the estimated total transaction price as they were considered constrained.

For the three and six months ended June 30, 2022, the Company recognized revenue of $2.7 million and $4.1 million, respectively, from the Takeda Collaboration Agreement, consisting of the platform technology enhancement services and the research and development services, which are delivered over time. As of June 30, 2022, the balance of estimated revenue expected to be recognized in the future related to performance obligations that are unsatisfied, or partially unsatisfied, pursuant to the Takeda Collaboration Agreement consisted of $1.0 million presented as a deferred revenue, current and $8.8 million presented as a deferred revenue, non-current, in the accompanying condensed consolidated balance sheet.

Note 7. California Institute of Regenerative Medicine Award

The Company has been awarded funding from California Institute of Regenerative Medicine ("CIRM") to develop certain internal programs. Under the terms of the funding both CIRM and the Company co-fund specified programs, under which funding is provided in developmental milestones determined as a part of the award. The Company is obligated to share potential future revenues for the related programs with CIRM. The percentage of revenues due to CIRM in the future is dependent on the amount of the award received and whether revenue is generated from product sales or through license fees. The maximum revenue sharing amount the Company may be required to pay to CIRM is equal to nine times the total amount awarded and paid to the Company. The Company has the option to decline any and all future grant amounts awarded by CIRM. As an alternative to revenue sharing, the Company has an option to convert any award to a loan, which such option the Company must exercise on or before ten business days after the FDA notifies the Company that it has accepted the Company's application for marketing authorization. In the event the Company exercises its right to convert any award to a loan, it would be obligated to repay the loan within ten business days of making such election. Repayment amounts due to CIRM vary dependent on when the award is converted to a loan, ranging from 60% of the award granted to the full amount received and interest at the rate of the three-month LIBOR rate plus 10% per annum. Since the Company may be required to repay some or all of the amounts awarded by CIRM, the Company accounted for this award as a liability as the Company's intention is to convert the award into a loan. Given the uncertainty in amounts due upon repayment, the Company has recorded amounts received without any discount or interest recorded, upon determination of amounts that would become due, the Company will adjust the amount of the liability accordingly.

In September 2018, the Company was granted an award in the amount of $4.0 million from CIRM to support the Company's preclinical studies for its P-PSMA-101 program. The Company received the full amount of the award based on achievement of specific developmental milestones. The amount of the award is presented as a deferred CIRM grant liability in the accompanying condensed consolidated balance sheets.

Note 8. Term Debt

In 2017, the Company entered into a loan and security agreement with Oxford Finance LLC ("Oxford"), which was subsequently amended ("Amended Loan Agreement"), pursuant to which the Company borrowed $20.0 million under a Term A loan and $10.0 million under a Term B loan.

In February 2022, the Company entered into a new Loan and Security Agreement ("2022 Loan Agreement") with Oxford. Pursuant to the terms of the 2022 Loan Agreement, the Company borrowed $60.0 million in term loans (the "Term Loans"), of which $31.6 million was used to repay the balance outstanding under the Amended Loan Agreement, including $0.2 million of accrued interest. Under the 2022 Loan Agreement the interest-only period is through April 1, 2025, followed by 23 equal monthly payments of principal and applicable interest. Upon occurrence of a qualifying equity event, the interest-only period may be extended through April 1, 2026, followed by 11 equal monthly payments of principal and applicable interest. As a result, all amounts outstanding under the 2022 Loan Agreement will mature on February 1, 2027 (the "Maturity Date"). In connection with the repayment of the balance outstanding under the Amended Loan Agreement, the Company incurred amendment and final payment fees of $1.5 million previously due on the earlier of (i) the maturity date, (ii) acceleration of any Term A or Term B loans, or (iii) the prepayment of the Term A or Term B loans.

The Company accounted for this amendment as debt modification in accordance with ASC Topic 470, *Debt* because the modification was not considered substantial.

The balance outstanding under the 2022 Loan Agreement bears interest at a floating per annum rate equal to 7.83% plus the greater of (a) the 30-day U.S. Dollar (USD) LIBOR rate and (b) 0.11%. The interest rate applicable to the Term Loans as of June 30, 2022 was 9.02% per annum. The 2022 Loan Agreement includes a provision addressing replacement of LIBOR with an alternate benchmark rate, which may include the Secured Overnight Financing Rate, when LIBOR is phased out. LIBOR is scheduled to be

phased out in June 2023. Consistent with the Amended Loan Agreement, the Company is required to make a final payment fee of 7.5% of the principal balance outstanding, payable on the earlier of (i) the Maturity Date, (ii) acceleration of any Term Loan, or (iii) the prepayment of the Term Loan. As of June 30, 2022, there was $60.0 million outstanding under the Term Loans. In connection with the Amended Loan Agreement, the Company previously incurred debt issuance costs of $1.6 million, which have been recorded as a debt discount and are being accreted to interest expense over the term of the Term Loans. Interest on the Term Loans, consisting of the stated interest rate, final payment fee and amortization of the discount, is being recognized under the effective interest method using a rate of 10.73%. As of June 30, 2022, the balance of the unamortized debt discount was $1.9 million. The balance of the accrued final payment fee was $1.8 million as of June 30, 2022 and is presented as other long-term liability in the accompanying condensed consolidated balance sheet.

The Company has an option to repay the outstanding debt under the 2022 Loan Agreement at any time in increments of $5.0 million, subject to a prepayment fee of 1.00% if the Term Loans are prepaid on or prior to February 22, 2024, after which no prepayment penalty would be applied.

The Company may use the proceeds from the Term Loans solely for its working capital requirements and to fund its general business operations. The Company's obligations under the 2022 Loan Agreement are secured by a first priority security interest in substantially all of its current and future assets, other than its intellectual property. In addition, the Company has also agreed not to encumber its intellectual property assets, except as permitted by the 2022 Loan Agreement. While any amounts are outstanding under the 2022 Loan Agreement, the Company is subject to a number of affirmative and restrictive covenants, including covenants regarding dispositions of property, business combinations or acquisitions, among other customary covenants. The Company is also restricted from declaring dividends or making other distributions or payments on its capital stock in excess of $0.3 million per calendar year, subject to limited exceptions. As of June 30, 2022, the Company was in compliance with all covenants under the 2022 Loan Agreement.

Note 9. Stockholders' Equity

Authorized Shares

In connection with the completion of the Company's initial public offering in July 2020, the Company amended its certificate of incorporation to authorize 250,000,000 shares of common stock, par value $0.0001 per share, and 10,000,000 shares of undesignated preferred stock, par value $0.0001 per share, that may be issued from time to time by the Company's board of directors in one or more series. Each share of common stock is entitled to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when declared by the Company's board of directors. Since the Company's inception, there have been no dividends declared.

Warrants

Pursuant to the Amended Loan Agreement, the Company issued Oxford (i) in 2017, a warrant to purchase 93,518 shares of common stock at an exercise price of $4.28 per share, which will expire in 2027 unless earlier exercised and (ii) in 2018 and 2019, warrants to purchase an aggregate of 27,604 shares of common stock at an exercise price of $7.25 per share, which will expire in 2028 and 2029, respectively, unless earlier exercised.

Note 10. Stock-Based Compensation

In July 2020, the Company's board of directors and stockholders approved and adopted the 2020 Equity Incentive Plan (the "2020 Plan"). Under the 2020 Plan, the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units and other stock or cash-based awards to individuals who are current employees, officers, directors or consultants of the Company. A total of 11,183,476 shares of common stock were approved to be initially reserved for issuance under the 2020 Plan. The number of shares that remained available for issuance under the Company's previous equity incentive plan as of the effective date of the 2020 Plan and shares subject to outstanding awards under the Company's previous equity incentive plan as of the effective date of the 2020 Plan that are subsequently canceled, forfeited or repurchased by the Company are added to the shares reserved under the 2020 Plan. The number of shares of common stock available for issuance under the 2020 Plan is automatically increased on the first day of each calendar year during the ten-year term of the 2020 Plan, beginning with January 1, 2021 and ending with January 1, 2030, by an amount equal to 5% of the outstanding number of shares of the Company's common stock on December 31 of the preceding calendar year or such lesser amount as determined by the Company's board of directors.

In February 2022, the Company's board of directors approved and adopted the 2022 Inducement Plan (the "Inducement Plan"). Under the Inducement Plan, the Company may grant nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other awards to individuals not previously employees or non-employee directors of the Company, as an inducement toward entering into employment with the Company. The maximum number of shares of common stock that may be issued under the Inducement Plan is 2,000,000 shares.

The following is a summary of the Company's stock option activity for the six months ended June 30, 2022:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Intrinsic Value (thousands)
Balance at January 1, 2022	9,899,707	$ 9.57		
Granted	3,448,889	3.75		
Exercised	(47,303)	1.56		
Forfeited/Cancelled	(723,068)	8.48		
Balance at June 30, 2022	12,578,225	$ 8.06	8.56	$ 331
Options vested and expected to vest as of June 30, 2022	12,578,225	$ 8.06	8.56	$ 331
Options vested and exercisable as of June 30, 2022	4,273,115	$ 9.81	7.64	$ 198

The aggregate intrinsic value of options exercised during the six months ended June 30, 2022 and 2021 was $58 thousand and $2.6 million, respectively, determined as of the date of exercise. The Company received $0.1 million and $0.4 million in cash from options exercised during the six months ended June 30, 2022 and 2021, respectively.

As of June 30, 2022, total unrecognized compensation cost related to stock options was $39.4 million, and the weighted-average period over which this cost is expected to be recognized was approximately 2.7 years.

The Company uses the Black-Scholes option pricing model to estimate the fair value of each option grant on the date of grant or any other measurement date. The assumptions that the Company used to determine the fair value of options granted to employees, non-employees and directors were as follows:

	Six Months Ended June 30,	
	2022	2021
Risk-free interest rate	1.3%–2.9%	0.5%–1.1%
Expected volatility	83%–92%	82%–84%
Expected term (years)	3.0–8.0	5.5–6.0
Dividend yield	—	—

The following is a summary of the Company's restricted stock unit ("RSU") activity for the six months ended June 30, 2022:

	Shares	Weighted Average Grant Date Fair Value
Balance at January 1, 2022	—	$ —
Granted	2,391,704	3.75
Vested	—	—
Forfeited/Cancelled	(116,437)	3.56
Balance at June 30, 2022	2,275,267	$ 3.76

RSU awards are share awards that, upon vesting, will deliver to the holder shares of the Company's common stock. The RSUs vest over four years from the grant date. The grant-date fair value is recognized as compensation expense over the vesting period. As of June 30, 2022, total unrecognized compensation cost related to RSUs was $7.7 million, and the weighted-average period over which this cost is expected to be recognized was approximately 3.5 years.

In July 2020, the Company's board of directors and stockholders approved and adopted the 2020 Employee Stock Purchase Plan (the "ESPP"), which became effective as of the pricing of the Company's initial public offering. A total of 615,000 shares of common stock were approved to be initially reserved for issuance under the ESPP. The number of shares of common stock available for issuance under the ESPP is automatically increased on the first day of each calendar year during the first ten-years of the term of the ESPP, beginning with January 1, 2021 and ending with January 1, 2030, by an amount equal to the lessor of (i) 1% of the outstanding number of shares of the Company's common stock on December 31 of the preceding calendar year, (ii) 1,230,000 shares of common stock or (iii) such lesser amount as determined by the Company's board of directors. Under the 2020 ESPP, substantially all employees can elect to have up to 15% of their annual compensation withheld to purchase up to 3,000 shares of common stock per purchase period, subject to certain limitations. The shares of common stock can be purchased over an offering period of six months and at a price of 85% of the fair market value per share of common stock on the first trading day of the applicable offering period or on the exercise date of the applicable offering period, whichever is less. Under applicable accounting guidance, the 2020 ESPP is classified as a compensatory plan. The initial purchase period commenced in March 2021. During the six months ended June 30, 2022, a total of 157,827 shares were purchased by the Company's employees under the 2020 ESPP resulting in net proceeds of $0.6 million.

The Company uses the Black-Scholes pricing model to estimate the fair value of the purchase rights issued under the ESPP on each offering date. The assumptions that the Company used to determine the fair value of the purchase rights issued to employees during the six months ended June 30, 2022 and 2021 were as follows:

	Six Months Ended June 30,	
	2022	2021
Risk-free interest rate	0.6%	0.1%
Expected volatility	84%	88%
Expected term (years)	0.5	0.5
Dividend yield	—	—

The Company recorded total stock-based compensation expense related to stock options, RSUs and the ESPP in the following expense categories of the accompanying condensed consolidated statements of operations and comprehensive loss (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Research and development	$ 2,646	$ 2,212	$ 5,074	$ 3,917
General and administrative	2,588	2,530	5,027	4,287
Total stock-based compensation expense	$ 5,234	$ 4,742	$ 10,101	$ 8,204

Note 11. Commitments and Contingencies

Operating Leases

As of June 30, 2022, the Company had operating leases for manufacturing, laboratory and office space in San Diego, California consisting of approximately 110,000 square feet with remaining lease terms of up to 7.5 years. During the six months ended June 30, 2022, the Company recorded an ROU asset of $4.4 million and a corresponding lease liability related to a sublease of a laboratory and office space facility, which commenced during the period. Certain of the Company's manufacturing, laboratory and office space lease agreements include two options to extend the term for a period of five years each. Additionally, the Company had operating leases for dedicated manufacturing suites at its contract manufacturers with remaining lease terms of up to 1.5 years.

During the six months ended June 30, 2022 and 2021, the Company recognized $3.7 million and $3.2 million, respectively, of operating lease expense, including a $0.6 million impairment of an ROU asset during the six months ended June 30, 2022. During the six months ended June 30, 2022, the Company paid $3.9 million for its operating leases. As of June 30, 2022, the weighted-average remaining lease term and weighted-average discount rate for operating leases were 6.7 years and 8.9%, respectively.

As of June 30, 2022, maturities of lease liabilities were as follows (in thousands):

Year ending December 31,		
2022 (remaining 6 months)	$	3,451
2023		7,057
2024		6,188
2025		6,374
2026		5,107
Thereafter		16,260
Total future lease payments		44,437
Imputed interest		(10,948)
Total lease liability balance		33,489
Less current portion of lease liability		6,686
Lease liability, net of current portion	$	26,803

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, contract research organizations, business partners and other parties with respect to certain matters including, but not limited to, losses arising from breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and certain of its executive officers that require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. The Company has not incurred any material costs as a result of such indemnifications and is not currently aware of any indemnification claims.

Legal Contingencies

In the ordinary course of business, the Company may face claims brought by third parties against the Company. The Company believes that there are currently no lawsuits, threats of litigation, or asserted or unasserted claims pending that could, individually or in the aggregate, have a material adverse effect on the Company's results of operations or financial condition.

Note 12. Net Loss Per Share

Net loss per share is computed by dividing net loss attributable to common stockholders for the period by the weighted average number of common shares outstanding during the period. Diluted loss per share reflects the additional dilution from potential issuances of common stock, such as stock issuable pursuant to the exercise of stock options and from purchases under the ESPP, as well as from the possible exercise of the outstanding warrants.

The Company's potentially dilutive securities, which include warrants to purchase common stock and common stock options, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted-average number of shares of common stock outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same.

The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	Six Months Ended June 30,	
	2022	2021
Outstanding stock options and RSUs	14,853,494	9,016,666
Warrants to purchase common stock	121,122	121,122
ESPP shares	41,137	—
	15,015,753	9,137,788

Note 13. Subsequent Event

Roche Collaboration Agreement

In July 2022, the Company entered the Roche Collaboration Agreement with Roche, pursuant to which the Company will grant to Roche: (i) an exclusive, worldwide license under certain Company intellectual property to develop, manufacture and commercialize allogeneic CAR-T cell therapy products from each of the Company's existing P-BCMA-ALLO1 and P-CD19CD20-ALLO1 programs (each a "Tier 1 Program"); (ii) an exclusive option to acquire an exclusive, worldwide license under certain Company intellectual property to develop, manufacture and commercialize allogeneic CAR-T cell therapy products from each of the Company's existing P-BCMACD19-ALLO1 and P-CD70-ALLO1 programs (each, a "Tier 2 Program"); (iii) an exclusive license under certain Company intellectual property to develop, manufacture and commercialize allogeneic CAR-T cell therapy products from the up to six Collaboration Programs (as defined below) designated by Roche; (iv) an option for a non-exclusive, commercial license under certain limited Company intellectual property to develop, manufacture and commercialize certain Roche proprietary cell therapy products for up to three solid tumor targets to be identified by Roche ("Licensed Products"); and (v) the right of first offer for two (2) early-stage existing programs within hematologic malignancies.

For each Tier 1 Program, the Company will perform development activities through a Phase 1 dose escalation clinical trial, and Roche is obligated to reimburse a specified percentage of certain costs incurred by the Company in its performance of such activities, up to a specified reimbursement cap for each Tier 1 Program. For each Tier 2 Program, the Company will perform research and development activities either through selection of a development candidate for IND-enabling studies or, subject to Roche's election and payment of an option maintenance fee, through completion of a Phase 1 dose escalation clinical trial. In addition, for each Tier 2 Program for which Roche exercises its option for an exclusive license, Roche is obligated to pay an option exercise fee. For each Tier 1 Program and Tier 2 Program, the Company will perform manufacturing activities until the completion of a technology transfer to Roche.

The parties will conduct an initial two-year research program to explore and preclinically test a specified number of agreed-upon next generation therapeutic concepts relating to allogeneic CAR-T cell therapies. Subject to Roche's election and payment of a specified fee, the parties would subsequently conduct a second research program of 18 months under which the parties would explore and preclinically test a specified number of additional agreed-upon next generation therapeutic concepts relating to allogeneic CAR-T therapies. Roche may designate up to six heme malignancy-directed, allogeneic CAR-T programs from the two research programs, for each of which the Company will perform research and development activities through selection of a development candidate for IND-enabling activities (each, a "Collaboration Program"). Upon its designation of each Collaboration Program, Roche is obligated to pay a designation fee. After the Company's completion of lead optimization activities for a Collaboration Program, Roche may elect to transition such program to Roche with a payment to the Company or terminate it. Alternatively, Roche may elect, for a limited number of Collaboration Programs, to have the Company conduct certain additional development and manufacturing activities through the completion of a Phase 1 dose escalation clinical trial, in which case Roche will pay certain milestones and reimburse a specified percentage of the Company's costs incurred in connection with such development and manufacturing activities. For each Collaboration Program, the Company will perform manufacturing activities until the completion of a technology transfer to Roche.

Under the Roche Collaboration Agreement, Roche is obligated to make an upfront payment to the Company of $110.0 million. The Company could also receive up to $110.0 million in near-term fees and milestone and other payments. Subject to Roche exercising its Tier 2 Program options, designating Collaboration Programs, and exercising its option for the Licensed Products commercial license and contingent on, among other things, the products from the Tier 1 Programs, optioned Tier 2 Programs and Collaboration Programs achieving specified development, regulatory, and net sales milestone events, the Company is eligible to receive certain reimbursements, fees and milestone payments, including the near-term fees and milestone and other payments described above, in the aggregate up to $6.0 billion, comprised of (i) $1.5 billion for the Tier 1 Programs; (ii) $1.1 billion for the Tier 2 Programs, (iii) $2.9 billion for the Collaboration Programs; and (iv) $415 million for the Licensed Products.

The Company is further entitled to receive, on a product-by-product basis, tiered royalty payments in the mid-single to low double digits on net sales of products from the Tier 1 Programs, optioned Tier 2 Programs and Collaboration Programs and in the low to mid-single digits for Licensed Products, in each case, subject to certain customary reductions and offsets. Royalties will be payable, on a product-by-product and country-by-country basis, until the latest of the expiration of the licensed patents covering such product in such country or ten years from first commercial sale of such product in such country.

The Roche Collaboration Agreement will become effective upon the expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and continue on a product-by-product and country-to-country basis until there is no remaining royalty or other payment obligations. The Roche Collaboration Agreement includes standard termination provisions, including for material breach or insolvency and for Roche's convenience. Certain of these termination rights can be exercised with respect to a particular product or license, as well as with respect to the entire Roche Collaboration Agreement.

2022 Underwritten Public Offering of Common Stock

On August 8, 2022, the Company completed the sale of an aggregate of 23,000,000 shares of its common stock in an underwritten public offering, at a price of $3.50 per share, including 3,000,000 shares sold pursuant to the full exercise of the underwriters' option to purchase additional shares. The net proceeds to the Company from the offering were approximately $75.3 million after deducting underwriting discounts and commissions and estimated offering expenses payable by the Company.

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 unaudited condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our audited consolidated financial statements and the related notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2021, or 2021 Annual Report, as filed with the Securities and Exchange Commission, or SEC. Operating results are not necessarily indicative of results that may occur in future periods. This discussion, particularly information with respect to our future results of operations or financial condition, business strategy and plans and objectives of management for future operations, includes forward-looking statements that involve risks and uncertainties as described under the heading "Special Note Regarding Forward-Looking Statements" in this Quarterly Report on Form 10-Q. You should review the disclosure under the heading "Risk Factors" in this Quarterly Report on Form 10-Q for a discussion of important factors that could cause our actual results to differ materially from those anticipated in these forward-looking statements.

Overview

We are a clinical-stage biopharmaceutical company dedicated to utilizing our proprietary genetic engineering platform technologies to create next-generation cell and gene therapeutics with the capacity to cure. We were incorporated in December 2014 and subsequently spun out from Transposagen, a company that has been developing genetic engineering technologies since 2003. Since our inception, our operations have focused on organizing and staffing our company, business planning, raising capital, in-licensing, developing and acquiring intellectual property rights and establishing and protecting our intellectual property portfolio, developing our genetic engineering technologies, identifying potential product candidates and undertaking research and development and manufacturing activities, including preclinical studies and clinical trials of our product candidates, and engaging in strategic transactions. We do not have any product candidates approved for sale and have not generated any revenue from product sales.

We have discovered and are developing a broad portfolio of product candidates in a variety of indications based on our core proprietary platforms, including our non-viral piggyBac DNA Delivery System, Cas-CLOVER Site-specific Gene Editing System and nanoparticle and AAV-based gene delivery technologies. Our core platform technologies have utility, either alone or in combination, across many cell and gene therapeutic modalities and enable us to engineer our portfolio of product candidates that are designed to overcome the primary limitations of current generation cell and gene therapeutics.

Within cell therapy, we believe our technologies allow us to create product candidates with engineered cells that engraft in the patient's body and drive lasting durable responses that may have the capacity to result in single treatment cures. Our CAR-T therapy portfolio consists of both autologous and allogeneic, or off-the-shelf, product candidates. We are advancing a broad pipeline and have multiple CAR-T product candidates in the clinical phase in both hematological and solid tumor oncology indications. Within gene therapy, we believe our technologies have the potential to create next-generation therapies that can deliver long-term, stable gene expression that does not diminish over time and that may have the capacity to result in single treatment cures.

Our most advanced investigational clinical programs are:

- **P-PSMA-101**, which is an autologous CAR-T product candidate targeting prostate-specific membrane antigen, or PSMA, being developed to treat patients with metastatic castrate-resistant prostate cancer, or mCRPC, and salivary gland carcinoma. We are currently evaluating P-PSMA-101 in a Phase 1 clinical trial. We presented encouraging preliminary results from our Phase 1 clinical trial of P-PSMA-101 in our first solid tumor indication on February 17, 2022 at ASCO-GU and may provide a further clinical update likely in 2023. We also have a second-generation program, P-PSMA-ALLO1, which is an allogeneic program, targeting PSMA utilizing a VH binder, in preclinical development.
- **P-BCMA-ALLO1**, which is a fully allogeneic CAR-T product candidate targeting BCMA, being developed to treat relapsed/refractory multiple myeloma patients. We are currently evaluating P-BCMA-ALLO1 in a Phase 1 clinical trial and we expect initial clinical data from our Phase 1 clinical trial in the second half of 2022 subject to coordination with Roche, as defined below. While P-BCMA-ALLO1 is currently manufactured at a contract manufacturing organization, or CMO, we previously announced our plan to transition manufacturing of P-BCMA-ALLO1 to our internal pilot manufacturing plant and these transition efforts are ongoing. In July 2022, we entered into a collaboration and license agreement, or the Roche Collaboration Agreement, with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc., or, collectively Roche, pursuant to which P-BCMA-ALLO1 will be exclusively licensed to Roche. Roche will be responsible for a majority of future development costs for P-BCMA-ALLO1 and will assume future development activities following the completion of the Phase 1 clinical trial.
- **P-MUC1C-ALLO1**, which is a fully allogeneic CAR-T product candidate for multiple solid tumor indications. We believe P-MUC1C-ALLO1 has the potential to treat a wide range of solid tumors derived from epithelial cells, such as breast, colorectal, lung, ovarian, pancreatic and renal cancers, as well as other cancers expressing a cancer-specific form of the Mucin 1 protein, or MUC1-C. We are currently evaluating P-MUC1C-ALLO1 in a Phase 1 clinical trial and we

expect initial clinical data from our Phase 1 clinical trial in the second half of 2022. P-MUC1C-ALLO1 is the first program for which clinical product will be sourced from our internal pilot manufacturing facility.

We manufacture these product candidates using our non-viral piggyBac DNA Delivery System. Our fully allogeneic CAR-T product candidates are developed using well-characterized cells derived from a healthy donor as starting material with the goal of enabling treatment of potentially hundreds of patients from a single manufacturing run. Doses are cryopreserved and stored at treatment centers for future off-the-shelf use. In addition, our allogeneic product candidates use our proprietary Cas-CLOVER site-specific Gene Editing System to reduce or eliminate reactivity, as well as our booster molecule technology for manufacturing scalability.

Our most advanced preclinical cell therapy program is:

- **P-CD19CD20-ALLO1**, which is a fully allogeneic CAR-T product candidate for B-cell hematological indications. This is our first Dual CAR program, which contains two fully functional CAR molecules to target cells that express at least one of the two intended targets. We believe that our ability to include two fully functional CAR molecules into a T cell could provide a competitive advantage compared to current therapies. We anticipate an IND filing and initiation of a Phase 1 clinical trial in the first half of 2023. P-CD19CD20-ALLO1 will also be exclusively licensed to Roche pursuant to the Roche Collaboration Agreement and Roche will be responsible for a majority of future development costs for P-CD19CD20-ALLO1 and will assume future development activities following the completion of the Phase 1 clinical trial.

Our gene therapy product candidates have been developed by utilizing our piggyBac technology together with AAV to overcome the major limitations of traditional AAV gene therapy. We believe that our approach can result in integration and long-term stable expression at potentially much lower doses than AAV technology alone, thus also conferring cost and tolerability benefits. Our eventual goal is to completely replace AAV with our non-viral nanoparticle technology, freeing future product development in gene therapy of AAV limitations.

Our most advanced gene therapy programs are:

- **P-OTC-101**, which is a liver-directed gene therapy combining piggyBac technology with AAV and nanoparticles for the *in vivo* treatment of Ornithine Transcarbamylase, or OTC, deficiency. OTC deficiency is an often fatal or morbid urea cycle disease caused by congenital mutations in the OTC gene with a high unmet medical need. We have made the decision to develop the P-OTC-101 program utilizing a hybrid of non-viral nanoparticle delivery system to deliver RNA and AAV to deliver DNA and are working on an updated timeline for the program.
- **P-FVIII-101**, which is a liver-directed gene therapy combining piggyBac technology with our nanoparticle delivery technology for the *in vivo* treatment of Hemophilia A. Hemophilia A is a bleeding disorder caused by a deficiency in Factor VIII production with a high unmet need. P-FVIII-101 utilizes piggyBac gene modification delivered via lipid nanoparticle that has demonstrated stable and sustained Factor VIII expression in animal models. Our P-FVIII-101 program is included in the collaboration and license agreement, or the Takeda Collaboration Agreement, with Takeda Pharmaceuticals USA, Inc., or Takeda, and Takeda will be responsible for all future development costs.

We expect our expenses and losses to increase substantially for the foreseeable future as we continue our development of, and seek regulatory approvals for, our product candidates, including P-PSMA-101 and P-MUC1C-ALLO1, and begin to commercialize any approved products. While we anticipate an overall increase in development costs as we continue to expand the number of product candidates in our pipeline and pursue clinical development of those candidates, we expect a decrease in our development costs on a per program basis as we are transitioning to our allogeneic platform. In addition, all or some of the development costs related to partnered gene therapy programs and cell therapy programs will be reimbursed by Takeda and Roche, respectively. We also expect our general and administrative expenses will increase for the foreseeable future to support our increased research and development and other corporate activities. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenditures on other research and development activities.

We do not expect to generate any revenues from product sales unless and until we successfully complete development and obtain regulatory approval for P-PSMA-101 and P-MUC1C-ALLO1, or any other product candidates, which will not be for at least the next several years, if ever. If we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution activities. Accordingly, until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through equity offerings, debt financings or other capital sources, including potential grants, collaborations, licenses or other similar arrangements. However, we may not be able to secure additional financing or enter into such other arrangements in a timely manner or on favorable terms, if at all. There can be no assurances that we will be able to secure such additional sources of funds to support our operations, or, if such funds are available to us, that such additional financing will be sufficient to meet our needs. Our failure to raise capital or enter into such other arrangements when needed would have a negative impact on our financial condition and could force us to delay, reduce or

terminate our research and development programs or other operations, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

The manufacturing process for our allogeneic product candidates is nearly identical to the process for our autologous product candidates, except for the gene editing and related steps. We work with a number of third-party contract manufacturing organizations for production of our product candidates. We also work with a variety of suppliers to provide our manufacturing raw materials including media, DNA and RNA components. We have completed construction of an internal pilot GMP manufacturing facility in San Diego, California adjacent to our headquarters to develop and manufacture preclinical materials and clinical supplies of our product candidates for Phase 1 and Phase 2 clinical trials in the future. We commenced GMP activity in the third quarter of 2021, however we expect that we will continue to rely on third parties for various manufacturing needs. In the future, we may also build one or more commercial manufacturing facilities for any approved product candidates.

Collaboration Agreements

Roche Collaboration Agreement

In July 2022, we entered the Roche Collaboration Agreement with Roche, pursuant to which we will grant to Roche: (i) an exclusive, worldwide license under certain of our intellectual property to develop, manufacture and commercialize allogeneic CAR-T cell therapy products from each of our existing P-BCMA-ALLO1 and P-CD19CD20-ALLO1 programs, or each, a Tier 1 Program; (ii) an exclusive option to acquire an exclusive, worldwide license under certain of our intellectual property to develop, manufacture and commercialize allogeneic CAR-T cell therapy products from our existing P-BCMACD19-ALLO1 and P-CD70-ALLO1 programs, or each, a Tier 2 Program; (iii) an exclusive license under certain of our intellectual property to develop, manufacture and commercialize allogeneic CAR-T cell therapy products from the up to six Collaboration Programs, as defined below, designated by Roche; (iv) an option for a non-exclusive, commercial license under certain limited intellectual property to develop, manufacture and commercialize certain Roche proprietary cell therapy products for up to three solid tumor targets to be identified by Roche, or Licensed Products; and (v) the right of first offer for two of our early-stage existing programs within hematologic malignancies.

For each Tier 1 Program, we will perform development activities through a Phase 1 dose escalation clinical trial, and Roche is obligated to reimburse a specified percentage of certain costs incurred by us in our performance of such activities, up to a specified reimbursement cap for each Tier 1 Program. For each Tier 2 Program, we will perform research and development activities either through selection of a development candidate for IND-enabling studies or, subject to Roche's election and payment of an option maintenance fee, through completion of a Phase 1 dose escalation clinical trial. In addition, for each Tier 2 Program for which Roche exercises its option for an exclusive license, Roche is obligated to pay us an option exercise fee. For each Tier 1 Program and Tier 2 Program, we will perform manufacturing activities until the completion of a technology transfer to Roche.

The parties will conduct an initial two-year research program to explore and preclinically test a specified number of agreed-upon next generation therapeutic concepts relating to allogeneic CAR-T cell therapies. Subject to Roche's election and payment of a fee, the parties would subsequently conduct a second research program of 18 months under which the parties would explore and preclinically test a specified number of additional agreed-upon next generation therapeutic concepts relating to allogeneic CAR-T therapies. Roche may designate up to six heme malignancy-directed, allogeneic CAR-T programs from the two research programs, for each of which we will perform research and development activities through selection of a development candidate for IND-enabling activities, or each, a Collaboration Program. Upon its designation of each Collaboration Program, Roche is obligated to pay a designation fee. After we complete lead optimization activities for a Collaboration Program, Roche may elect to transition such program to Roche with a payment to us or terminate it. Alternatively, Roche may elect, for a limited number of Collaboration Programs, to have us conduct certain additional development and manufacturing activities through the completion of a Phase 1 dose escalation clinical trial, in which case Roche will pay certain milestones and reimburse a specified percentage of our costs incurred in connection with such development and manufacturing activities. For each Collaboration Program, we will perform manufacturing activities until the completion of a technology transfer to Roche.

Under the Roche Collaboration Agreement, Roche is obligated to make an upfront payment to us of $110.0 million. We could also receive up to $110.0 million in near-term fees and milestone and other payments. Subject to Roche exercising its Tier 2 Program options, designating Collaboration Programs, and exercising its option for the Licensed Products commercial license and contingent on, among other things, the products from the Tier 1 Programs, optioned Tier 2 Programs and Collaboration Programs achieving specified development, regulatory, and net sales milestone events, we are eligible to receive certain reimbursements, fees and milestone payments, including the near-term fees and milestone payments described above, in the aggregate up to $6.0 billion, comprised of (i) $1.5 billion for the Tier 1 Programs; (ii) $1.1 billion for the Tier 2 Programs, (iii) $2.9 billion for the Collaboration Programs; and (iv) $415 million for the Licensed Products.

We are further entitled to receive, on a product-by-product basis, tiered royalty payments in the mid-single to low double digits on net sales of products from the Tier 1 Programs, optioned Tier 2 Programs and Collaboration Programs and in the low to mid-single digits for Licensed Products, in each case, subject to certain customary reductions and offsets. Royalties will be payable, on a product-by-product and country-by-country basis, until the latest of the expiration of the licensed patents covering such product in such country or ten years from first commercial sale of such product in such country.

The Roche Collaboration Agreement will become effective upon the expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and continue on a product-by-product and country-to-country basis until there is no remaining royalty or other payment obligations. The Roche Collaboration Agreement includes standard termination provisions, including for material breach or insolvency and for Roche's convenience. Certain of these termination rights can be exercised with respect to a particular product or license, as well as with respect to the entire Roche Collaboration Agreement.

Takeda Collaboration Agreement

In October 2021, we entered into the Takeda Collaboration Agreement, pursuant to which we granted to Takeda a worldwide exclusive license under our piggyBac, Cas-CLOVER, biodegradable DNA and RNA nanoparticle delivery technology and other proprietary genetic engineering platforms to research, develop, manufacture and commercialize gene therapy products for certain indications, including Hemophilia A. We collaborate with Takeda to initially develop up to six *in vivo* gene therapy programs and Takeda also has an option to add two additional programs to the collaboration. We are obligated to lead research activities up to candidate selection, after which Takeda is obligated to assume responsibility for further development, manufacturing and commercialization of each program.

Under the Takeda Collaboration Agreement, Takeda made an upfront payment to us of $45.0 million. Takeda is also obligated to provide funding for all collaboration program development costs including our P-FVIII-101 program; provided that we are obligated to perform certain platform development activities at our own cost. Timelines for P-FVIII-101 and other programs subject to the Takeda Collaboration Agreement will be driven by Takeda. Under the Takeda Collaboration Agreement, we are eligible to receive preclinical milestone payments that could potentially exceed $82.5 million in the aggregate if preclinical milestones for all six programs are achieved. We are also eligible to receive future clinical development, regulatory and commercial milestone payments of $435.0 million in the aggregate per target, with a total potential deal value over the course of the collaboration of up to $2.7 billion, if milestones for all six programs are achieved and up to $3.6 billion if the milestones related to the two optional programs are also achieved. We are entitled to receive tiered royalty payments on net sales in the mid-single to low double digits, subject to certain standard reductions and offsets. Royalties will be payable, on a product-by-product and country-by-country basis, until the latest of the expiration of the licensed patents covering such product in such country, ten years from first commercial sale of such product in such country, or expiration of regulatory exclusivity for such product in such country.

In-License Agreements

Below is a summary of our key license agreements. For a more detailed description of these and our other license agreements, see the section titled "Business—In-License Agreements" and Note 11 to our annual consolidated financial statements included in our 2021 Annual Report.

- License Agreement with Janssen Biotech Inc., or the Janssen Agreement, pursuant to which we obtained exclusive worldwide rights to research, develop, manufacture and commercialize pharmaceutical products comprising autologous CAR-modified T-cells or any CAR-modified natural killer or CAR-modified natural-killer-like cells expressing certain Centyrin molecules CAR-modified for the treatment or prevention of any disease in humans. This is the binding technology we use in our P-PSMA-101 product candidate.
- 2017 Commercial License Agreement with TeneoBio, Inc. (a subsidiary of Amgen Inc.), or the 2017 TeneoBio Agreement, pursuant to which we obtained exclusive worldwide rights to use and develop pharmaceutical products comprising allogeneic T-cells expressing a CAR molecule containing certain heavy chain sequences provided by TeneoBio for the treatment of human disease. We use this heavy-chain-only binder in our P-BCMA-ALLO1 product candidate.

- 2018 Commercial License Agreement with TeneoBio, or the 2018 TeneoBio Agreement, for the development and use of TeneoBio's human heavy-chain-only antibodies in CAR-T cell therapies. Under the terms of the 2018 TeneoBio Agreement, we have the option to obtain exclusive rights to research, develop and commercialize up to a certain number of targets, including but not limited to the binders used in our P-CD19CD20-ALLO1 and P-PSMA-ALLO1 product candidates.
- License Agreement with Xyone Therapeutics, Inc. (as successor-in-interest to Genus Oncology, LLC), or the Xyone Agreement, pursuant to which we obtained an exclusive worldwide license under certain patents and a non-exclusive worldwide license under certain know-how controlled by Xyone to research, develop and commercialize pharmaceutical products incorporating CAR cells expressing antibodies and derivatives thereof targeting MUC1-C, or a Xyone licensed product, and a non-exclusive worldwide license under certain patents and know-how controlled by Xyone to research, develop and commercialize companion diagnostics for the treatment, prevention and palliation of human diseases and conditions. We use a Xyone antibody or derivative thereof targeting MUC1-C as a binder in our P-MUC1C-ALLO1 product candidate.

CIRM Grant Funding

In 2017, we were granted an award in the amount of $19.8 million from California Institute of Regenerative Medicine, or CIRM, to support our clinical trial for P-BCMA-101. To date we have received a total of $19.7 million from this grant and we may receive up to $0.1 million in future grant payments upon closeout of our clinical trial for this program. In the fourth quarter of 2021 we made the decision to wind down clinical development of the P-BCMA-101 program and derecognized the liability related to amount of the award previously received. In 2018, we were granted an additional award in the amount of $4.0 million from CIRM to support our preclinical studies for P-PSMA-101, of which we have received all proceeds from this grant. The terms of these awards include an option to repay the grant or convert it to a royalty obligation upon commercialization of the program. Based upon the terms of the grant agreements, we initially record proceeds as a liability when received and subsequently reassess based on our intention to repay the amounts associated with awards or convert them to a royalty obligation.

Components of Our Results of Operations

Revenues

Collaboration Revenue

Collaboration revenue consists of revenue recognized from our collaboration and license agreement with Takeda and reflects the timing and pattern in which we deliver the contractual deliverables to Takeda.

Operating Expenses

Research and Development

Research and development expenses consist primarily of external and internal costs incurred for our research and development activities, including development of our platform technologies, our drug discovery efforts and the development of our product candidates.

External costs include:

- expenses incurred in connection with the preclinical and clinical development of our product candidates and research programs, including under agreements with third parties, such as consultants, contractors and contract research organizations, or CROs;
- the cost of developing and scaling our manufacturing process and manufacturing drug products for use in our preclinical studies and clinical trials, including under agreements with third parties, such as consultants, contractors and contract manufacturing organizations, or CMOs;
- payments made under third-party licensing agreements;
- the cost of manufacturing clinical materials for use in our preclinical studies and clinical trials; and
- laboratory supplies and research materials.

Internal costs include:

- personnel-related expenses, consisting of employee salaries, related benefits and stock-based compensation expense for employees engaged in research, development and manufacturing functions;

- the cost to develop manufacturing capability at our San Diego facility for manufacture of cell therapies for use in clinical trials; and
- facilities, depreciation and other expenses, consisting of direct and allocated expenses for rent and maintenance of facilities and insurance.

We expense research and development costs as incurred. External expenses are recognized based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers or our estimate of the volume of service that has been performed at each reporting date. Upfront payments and milestone payments made for the licensing of technology are related to clinical stage programs and expensed as research and development in the period in which they are incurred. Advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses or other long-term assets. These amounts are expensed as the related goods are delivered or the services are performed.

At any one time, we are working on multiple research programs. We track external costs by the stage of program, clinical or preclinical. Our internal resources, employees and infrastructure are not directly tied to any one program and are typically deployed across multiple programs. As such, we do not track internal costs on a specific program basis.

Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to CRO activity and manufacturing expenses. We expect that our research and development expenses will increase substantially in connection with our planned preclinical and clinical development activities in the near term and in the future, including in connection with our ongoing Phase 1 trial of P-PSMA-101 for the treatment of patients with mCRPC, Phase 1 trial of P-BCMA-ALLO1 for the treatment of patients with relapsed/refractory multiple myeloma and Phase 1 trial of P-MUC1C-ALLO1 for the treatment of patients with solid tumor cancers and additional clinical programs expected to commence as we expand our pipeline of drug candidates. We cannot accurately estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of any of our product candidates. Our development costs may vary significantly based on factors such as:

- the number and scope of preclinical and IND-enabling studies;
- per patient trial costs;
- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the cost and timing of manufacturing our product candidates;
- the phase of development of our product candidates;
- the efficacy and safety profile of our product candidates;
- the extent to which we establish additional licensing agreements; and
- whether we choose to partner any of our product candidates and the terms of such partnership.

A change in the outcome of any of these variables with respect to the development of any of our product candidates could significantly change the cost structure and timing associated with the development of respective product candidates. We may never succeed in obtaining regulatory approval for any of our product candidates. We may obtain unexpected results from our clinical trials and preclinical studies.

General and Administrative

General and administrative expenses consist primarily of salaries and related costs, including stock-based compensation, for personnel in executive, finance and administrative functions. General and administrative expenses also include direct and allocated facility-related costs as well as professional fees for legal, patent, consulting, investor and public relations, and accounting and audit services. We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research activities and development of our product candidates, including P-PSMA-101, P-BCMA-ALLO1 and P-MUC1C-ALLO1, and begin to commercialize any approved products.

Other Income (Expense)

Interest Expense

Interest expense consists of interest expense on outstanding borrowings under our loan agreement and amortization of debt discount and debt issuance costs.

Other Income (Expense), Net

Other income (expense), net consists of interest income and miscellaneous income and expense unrelated to our core operations. Interest income is comprised of interest earned on our available-for-sale securities.

Results of Operations

Comparison of the Three Months Ended June 30, 2022 and 2021

The following table summarizes our results of operations (in thousands):

	Three Months Ended June 30,		
	2022	2021	Change
Revenues:			
Collaboration revenue	$ 2,700	$ —	$ 2,700
Total revenue	2,700	—	2,700
Operating expenses:			
Research and development	35,008	36,008	(1,000)
General and administrative	9,237	8,871	366
Total operating expenses	44,245	44,879	(634)
Loss from operations	(41,545)	(44,879)	3,334
Other income (expense):			
Interest expense	(1,543)	(843)	(700)
Other income (expense), net	52	17	35
Net loss before income tax	(43,036)	(45,705)	2,669
Income tax expense	—	—	—
Net loss	$ (43,036)	$ (45,705)	$ 2,669

Collaboration Revenue

Collaboration revenue of $2.7 million for the three months ended June 30, 2022 represents revenue recognized from the Takeda Collaboration Agreement that we entered into in the fourth quarter of 2021 and related to the research services we performed for Takeda.

Research and Development Expenses

The following table summarizes our research and development expenses (in thousands):

	Three Months Ended June 30,		
	2022	2021	Change
External costs:			
Clinical stage programs[1]	$ 8,628	$ 12,726	$ (4,098)
Preclinical stage programs and other unallocated expenses	7,759	9,442	(1,683)
Internal costs:			
Personnel	14,844	10,876	3,968
Facilities and other	3,777	2,964	813
Total research and development expenses	$ 35,008	$ 36,008	$ (1,000)

(1) Clinical stage programs include costs related to P-BCMA-ALLO1, P-MUC1C-ALLO1, and P-PSMA-101 programs for the three months ended June 30, 2022 and costs related to P-BCMA-101 and P-PSMA-101 programs for the three months ended June 30, 2021.

Research and development expenses were $35.0 million for the three months ended June 30, 2022, compared to $36.0 million for the three months ended June 30, 2021. The decrease in research and development expenses of $1.0 million was primarily due to a decrease of $4.1 million in external costs related to our clinical stage programs, driven mainly by the wind-down of our clinical development activities associated with the P-BCMA-101 program, as announced in the fourth quarter of 2021, and an early termination and accelerated expense of a contract with one of our autologous contract manufacturers in the first quarter of 2022, partially offset by increases in the number of ongoing clinical trials, including enrollment and manufacturing for the P-PSMA-101, P-BCMA-ALLO1, and the P-MUC1C-ALLO1 Phase 1 clinical trials, and a $1.7 million decrease in external costs related to our preclinical stage programs, driven mainly by the transition of the P-BCMA-ALLO1 and P-MUC1C-ALLO1 programs to clinical stage. The increase of $4.0 million in personnel expenses was a result of an increase in headcount which included a $0.4 million increase in stock-based compensation expense.

General and Administrative Expenses

General and administrative expenses were $9.2 million for the three months ended June 30, 2022, compared to $8.9 million for the three months ended June 30, 2021. The increase in general and administrative expenses of $0.4 million was primarily due to an increase of $0.2 million in personnel expenses as a result of an increase in headcount which included a $0.1 million increase in stock-based compensation expense.

Interest Expense

Interest expense was $1.5 million for the three months ended June 30, 2022, compared to $0.8 million for the three months ended June 30, 2021 and consisted of interest on the principal balance outstanding under our term loans with Oxford Finance LLC, or Oxford. The increase in interest expense of $0.7 million was primarily due to an increase in principal outstanding related to the modification of the terms of our loan pursuant to the 2022 Loan Agreement, as defined below, which we entered into in February 2022.

Other Income (Expense), Net

Other income, net was less than $0.1 million for each of the three months ended June 30, 2022 and 2021.

Comparison of the Six Months Ended June 30, 2022 and 2021

The following table summarizes our results of operations (in thousands):

	Six Months Ended June 30,		
	2022	2021	Change
Revenues:			
Collaboration revenue	$ 4,135	$ —	$ 4,135
Total revenue	4,135	—	4,135
Operating expenses:			
Research and development	83,858	65,103	18,755
General and administrative	18,782	17,240	1,542
Total operating expenses	102,640	82,343	20,297
Loss from operations	(98,505)	(82,343)	(16,162)
Other income (expense):			
Interest expense	(2,620)	(1,681)	(939)
Other income (expense), net	32	5	27
Net loss before income tax	(101,093)	(84,019)	(17,074)
Income tax expense	—	—	—
Net loss	$ (101,093)	$ (84,019)	$ (17,074)

Collaboration Revenue

Collaboration revenue of $4.1 million for the six months ended June 30, 2022 represents revenue recognized from the Takeda Collaboration Agreement that we entered into in the fourth quarter of 2021 and related to the research services we performed for Takeda.

Research and Development Expenses

The following table summarizes our research and development expenses (in thousands):

	Six Months Ended June 30,		
	2022	2021	Change
External costs:			
Clinical stage programs(1)	$ 31,656	$ 22,947	$ 8,709
Preclinical stage programs and other unallocated expenses	15,822	15,460	362
Internal costs:			
Personnel	29,409	20,993	8,416
Facilities and other	6,971	5,703	1,268
Total research and development expenses	$ 83,858	$ 65,103	$ 18,755

(1) Clinical stage programs include costs related to P-BCMA-ALLO1, P-MUC1C-ALLO1, and P-PSMA-101 programs for the six months ended June 30, 2022 and costs related to P-BCMA-101 and P-PSMA-101 programs for the six months ended June 30, 2021.

Research and development expenses were $83.9 million for the six months ended June 30, 2022, compared to $65.1 million for the six months ended June 30, 2021. The increase in research and development expenses of $18.8 million was primarily due to an increase of $8.7 million in external costs related to our clinical stage programs from an increase in the number of ongoing clinical trials, including enrollment and manufacturing for the P-PSMA-101 Phase 1, the P-BCMA-ALLO1 Phase 1, and the P-MUC1C-ALLO1 Phase 1 clinical trials, an increase of $8.4 million in personnel expenses as a result of an increase in headcount which included a $1.2 million increase in stock-based compensation expense, and a $1.3 million increase in internal facilities and other costs. The increase in external costs related to our clinical stage programs also includes a loss on a contract termination related to an early termination and accelerated expense of a contract with one of our autologous contract manufacturers during the six months ended June 30, 2022, consisting of future contractual payment obligations, a write off of deferred milestone payments previously made to our autologous contract manufacturer, and an impairment of a related right-of-use asset, partially offset by the wind-down of our clinical development activities associated with the P-BCMA-101 program.

General and Administrative Expenses

General and administrative expenses were $18.8 million for the six months ended June 30, 2022, compared to $17.2 million for the six months ended June 30, 2021. The increase in general and administrative expenses of $1.5 million was primarily due to an increase of $1.3 million in personnel expenses as a result of an increase in headcount which included a $0.7 million increase in stock-based compensation expense.

Interest Expense

Interest expense was $2.6 million for the six months ended June 30, 2022, compared to $1.7 million for the six months ended June 30, 2021 and consisted of interest on the principal balance outstanding under our term loans with Oxford. The increase in interest expense of $0.9 million was primarily due to an increase in principal outstanding related to the modification of the terms of our loan pursuant to the 2022 Loan Agreement, as defined below, which we entered into in February 2022.

Other Income (Expense), Net

Other income, net was less than $0.1 million for each of the six months ended June 30, 2022 and 2021.

Liquidity and Capital Resources

We were incorporated in December 2014 and subsequently spun out from Transposagen, a company that has been developing genetic engineering technologies since 2003. Since our inception in 2014, we have incurred significant operating losses and negative cash flows from operations and have relied on our ability to fund our operations primarily through equity and debt financings and collaborations. For the six months ended June 30, 2022 we have incurred a net loss of $101.1 million, and negative cash flows from operations of $91.1 million. We expect to continue to incur net losses and negative cash flows from operations for at least the next several years. As of June 30, 2022, we had an accumulated deficit of $508.0 million.

Our operations have focused on organizing and staffing our company, business planning, raising capital, in-licensing and acquiring intellectual property rights and establishing and protecting our intellectual property portfolio, developing our genetic engineering technologies, identifying potential product candidates and undertaking research and development and manufacturing activities, including preclinical studies and clinical trials of our product candidates, and engaging in strategic transactions. Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures, and to a lesser extent, general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses. We have not yet commercialized any of our product candidates and we do not expect to generate revenue from sales of any product candidates for several years, if at all. We have funded our operations primarily through the sale of equity, debt financings and collaborations. Since our inception, we have raised $224.0 million of gross proceeds from the sale of our common stock in our initial public offering in July 2020, raised an aggregate of $334.3 million of gross proceeds from the sale of shares of our redeemable convertible preferred stock, received $60.0 million of gross proceeds from borrowings under our loan agreement and received an aggregate of $23.8 million in grant funding from CIRM. In 2021, we entered into the Takeda Collaboration Agreement and received an upfront payment of $45.0 million. In July 2022, we entered into the Roche Collaboration Agreement with Roche. Under the Roche Collaboration Agreement, subject to regulatory clearance, Roche is obligated to make an upfront payment to us of $110.0 million and the Company could also receive up to $110.0 million in near-term fees and milestone and other payments, and all of which has not yet been received. Additionally, in August, 2022, we completed the sale of an aggregate of 23,000,000 shares of our common stock in an underwritten public offering, at a price of $3.50 per share, including 3,000,000 shares sold pursuant to the full exercise of the underwriters' option to purchase additional shares. The net proceeds to us from the offering were approximately $75.3 million after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

We expect that our cash, cash equivalents and short-term investments as of June 30, 2022, of $142.6 million, in combination with the upfront payment of $110.0 million to be received pursuant to the Roche Collaboration Agreement and the net proceeds from the underwritten public offering of approximately $75.3 million, will be sufficient to fund our operations for at least the next twelve months from the date of issuance of the financial statements included in this Quarterly Report on Form 10-Q. In the long term, we will need additional financing to support our continuing operations and pursue our business strategy.

Loan Agreement

In 2017, we entered into a loan and security agreement with Oxford, as subsequently amended, or Amended Loan Agreement, pursuant to which we drew a Term A loan in the amount of $20.0 million and a Term B loan, in the amount of $10.0 million for a total outstanding balance of $30.0 million.

In February 2022, we entered into a new Loan and Security Agreement, or the 2022 Loan Agreement, with Oxford. Pursuant to the terms of the 2022 Loan Agreement we borrowed $60.0 million in term loans, a portion of which was used to repay the balance outstanding under the Amended Loan Agreement. Under the 2022 Loan Agreement the initial interest-only period is through April 1, 2025, followed by 23 equal monthly payments of principal and applicable interest. Upon the occurrence of a qualifying equity event as set forth in the 2022 Loan Agreement, the interest-only period may be extended through April 1, 2026, followed by 11 equal monthly payments of principal and applicable interest. As a result, all amounts outstanding under the 2022 Loan Agreement will mature on February 1, 2027. The balance outstanding under the 2022 Loan Agreement bears interest at a floating per annum rate equal to 7.83% plus the greater of (a) the 30-day U.S. Dollar (USD) LIBOR rate and (b) 0.11%. As of June 30, 2022, the interest rate applicable to our Term Loans borrowing was 9.02%.

In connection with the repayment of the balance outstanding under the Amended Loan Agreement, we incurred amendment and final payment fees of $1.5 million previously due on the earlier of (i) the maturity date, (ii) acceleration of any Term A or Term B loans, or (iii) the prepayment of the Term A or Term B loans. We have an option to repay the outstanding debt under the 2022 Loan Agreement at any time in increments of $5.0 million, subject to a prepayment fee of 1.0% if the term loans are prepaid on or prior to February 22, 2024, after which no prepayment penalty would be applied. Consistent with the Amended Loan Agreement, there is a 7.5% final payment fee payable on the earlier of (i) the new maturity date, (ii) acceleration of the new loan, or (iii) the prepayment of the new loan.

On November 30, 2020, ICE Benchmark Administration, with the support of the United States Federal Reserve and the FCA, announced plans to consult on ceasing publication of USD LIBOR on December 31, 2021 for only the one week and two-month USD LIBOR tenors, and on June 30, 2023 for all other USD LIBOR tenors. Various central bank committees and working groups continue to discuss replacement of benchmark rates, the process for amending existing LIBOR-based contracts, and the potential economic impacts of different alternatives. The Alternative Reference Rates Committee has identified the Secured Overnight Financing Rate, or SOFR, as its preferred alternative rate for USD LIBOR. SOFR is a measure of the cost of borrowing cash overnight, collateralized by U.S. Treasury securities, and is based on directly observable U.S. Treasury-backed repurchase transactions.

Cash Flows

The following table sets forth the primary sources and uses of cash and cash equivalents (in thousands):

	Six Months Ended June 30,	
	2022	2021
Cash used in operating activities	$ (91,053)	$ (70,144)
Cash provided by (used in) investing activities	(81,572)	185,444
Cash provided by financing activities	29,263	427
Net increase (decrease) in cash and cash equivalents	$ (143,362)	$ 115,727

Cash Used in Operating Activities

During the six months ended June 30, 2022, net cash used in operating activities was $91.1 million, primarily resulting from our net loss of $101.1 million and net cash decrease from changes in our operating assets and liabilities of $4.8 million, partially offset by non-cash expenses of $14.9 million. Non-cash charges consisted primarily of $10.1 million in stock-based compensation, $5.7 million in non-cash loss on a termination of a contract with one of our autologous contract manufacturers and $2.5 million in depreciation and amortization expense, partially offset by $3.9 million in decrease in deferred revenue. Net cash decrease from changes in our operating

assets and liabilities for the six months ended June 30, 2022 consisted primarily of a $5.9 million decrease in accounts payable, partially offset by $1.0 million in decrease in prepaid expenses and other current assets.

During the six months ended June 30, 2021, net cash used in operating activities was $70.1 million, primarily resulting from our net loss of $84.0 million, offset by non-cash expenses of $10.9 million, and net cash increase from changes in our operating assets and liabilities of $3.0 million. Non-cash charges consisted primarily of $8.2 million in stock-based compensation and $2.2 million in depreciation and amortization expense. Net cash increase from changes in our operating assets and liabilities for the six months ended June 30, 2021 consisted primarily of a $3.7 million increase in accounts payable and a $1.7 million decrease in prepaid expenses and other current assets partially offset by a $2.7 million decrease in accrued expenses and other liabilities.

Cash Provided by (Used in) Investing Activities

During the six months ended June 30, 2022, cash used in investing activities was $81.6 million, consisting of $79.6 million in purchases of short-term investments and $2.0 million in purchases of property and equipment.

During the six months ended June 30, 2021, net cash provided by investing activities was $185.4 million, consisting primarily of proceeds from maturities of short-term investments of $187.5 million partially offset by purchases of property and equipment of $2.1 million.

The timing of purchases and sales of our short-term investments is driven by available cash balance and maturity of existing investments. The purchase of property and equipment for all periods related to equipment purchases as we expanded our research and development and manufacturing activities, in addition to corporate office space.

Cash Provided by Financing Activities

During the six months ended June 30, 2022, net cash provided by financing activities was $29.3 million, consisting of proceeds from the 2022 Loan Agreement of $28.6 million, net of debt issuance costs and repayment of the Amended Loan Agreement, and $0.7 million of proceeds from purchases under our ESPP and exercises of stock options.

During the six months ended June 30, 2021, net cash provided by financing activities was $0.4 million, representing proceeds from the exercises of stock options.

Contractual Obligations and Commitments

We enter into contracts in the normal course of business with contract research organizations, CMOs and other third parties for preclinical research studies, clinical trials and testing and manufacturing services. These contracts do not contain minimum purchase commitments and are cancelable by us upon prior written notice. Payments due upon cancellation consist of payments for services provided or expenses incurred, including noncancelable obligations of our service providers, up to one year after the date of cancellation. The amount and timing of such payments are not known.

We have also entered into several license agreements under which we are obligated to make aggregate milestone payments upon the achievement of specified preclinical, clinical and regulatory milestones as well as royalty payments. The payment obligations under these license agreements are contingent upon future events, such as our achievement of specified milestones or generating product sales. We record these milestone payments when they are estimable and probable to be achieved. Estimating the timing or likelihood of achieving these milestones or generating future product sales requires significant judgment and is subject to uncertainty.

During the six months ended June 30, 2022, except for modification of our term loan disclosed in Note 8 and the lease commitments disclosed in Note 11 to the condensed consolidated financial statements in this Quarterly Report on Form 10-Q, there were no significant changes to our contractual obligations and commitments described under Management’s Discussion and Analysis of Financial Condition and Results of Operations in our 2021 Annual Report.

Critical Accounting Policies and Significant Judgments and Estimates

Management's discussion and analysis of our financial condition and results of operations are based upon our financial statements, which are prepared in accordance with accounting principles that are generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities, related disclosure of contingent liabilities at the date of the financial statements, and the reported amounts of expenses and other income during the reporting period. We continually evaluate our estimates and judgments, the most critical of which are those related to preclinical and clinical study accruals and stock-based compensation costs. We base our estimates and judgments on historical experience and other factors that we believe to be reasonable under the circumstances. Materially different results can occur as circumstances change and additional information becomes known.

There were no significant changes during the six months ended June 30, 2022 to the items that we disclosed as our critical accounting policies and estimates in Note 2 to our audited consolidated financial statements included in our 2021 Annual Report.

JOBS Act

We are an emerging growth company, as defined in Section 2(a) of the Securities Act of 1933, as amended, or the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. The JOBS Act permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We have elected to use this the extended transition period under the JOBS Act until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our consolidated financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates. The JOBS Act also allows up to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including relief from the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, less extensive disclosure obligations regarding executive compensation in our registration statements, periodic reports and proxy statements, exemptions from the requirements to hold a nonbinding advisory vote on executive compensation, and exemptions from stockholder approval of any golden parachute payments not previously approved. We may also elect to take advantage of other reduced reporting requirements in future filings. As a result, our stockholders may not have access to certain information that they may deem important and the information that we provide to our stockholders may be different than, and not comparable to, information presented by other public reporting companies.

We will remain an emerging growth company until the earliest to occur of: (1) the last day of the fiscal year in which we have more than $1.07 billion in annual revenue; (2) the date we qualify as a "large accelerated filer," with at least $700.0 million of equity securities held by non-affiliates; (3) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period; and (4) December 31, 2025.

We are also a smaller reporting company, as defined in the Securities Exchange Act of 1934. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as (i) our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Recent Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position, results of operations or cash flows is disclosed in Note 2 to our condensed consolidated financial statements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

As of June 30, 2022, we had cash, cash equivalents and short-term investments of $142.6 million. Cash consists of deposits with financial institutions. Interest income is sensitive to changes in the general level of interest rates. However, due to the nature of these investments, a hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our consolidated financial statements.

As of June 30, 2022, we had $60.0 million of borrowings outstanding under the 2022 Loan Agreement bearing interest at a variable rate equal to 30-day LIBOR plus 7.83%, subject to a floor of 7.94%. A hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our consolidated financial statements. LIBOR is scheduled to be phased out in June 2023. Our 2022 Loan Agreement includes provision addressing replacement of LIBOR with an alternate benchmark rate, which may include SOFR, when LIBOR is phased out, however a new standard has not yet been established. The consequences of a change in benchmark rate cannot be entirely predicted, but could result in higher interest rates on the principal amount outstanding under our 2022 Loan Agreement.

Foreign Currency Exchange Risk

To date, foreign currency transaction gains and losses have not been material to our consolidated financial statements, and we have not had a formal hedging program with respect to foreign currency. Our expenses are generally denominated in U.S. dollars. However, we have contracted with a limited number of foreign vendors located in Europe and Canada and may contract with foreign vendors in the future. Our operations may be subject to fluctuations in foreign currency exchange rates in the future. A hypothetical 10% change in exchange rates during any of the periods presented would not have had a material impact on our consolidated financial statements.

Effects of Inflation

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

Item 4. Controls and Procedures.

Disclosure Controls and Procedures

We are responsible for maintaining disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Disclosure controls and procedures are controls and other procedures designed to ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Principal Executive Officer and Principal Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Based on our management's evaluation, the Principal Executive Officer and Principal Financial Officer have concluded that our disclosure controls and procedures were effective as of June 30, 2022.

Changes in Internal Control Over Financial Reporting

There have been 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 quarter ended June 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

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

Item 1A. Risk Factors.

An investment in our common stock is speculative and involves a high degree of risk. You should consider carefully the risks described below, together with the other information contained in this Quarterly Report on Form 10-Q, including our condensed consolidated financial statements and the related notes and in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" before deciding whether to purchase, hold or sell shares of our common stock. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment. This Quarterly Report on Form 10-Q also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of a number of factors, including the risks described below. See the section titled "Special Note Regarding Forward-Looking Statements." The risk factors set forth below with an asterisk (*) next to the title contain changes to the description of the risk factors associated with our business previously disclosed in Item 1A of our 2021 Annual Report on Form 10-K for the year ended December 31, 2021.

Summary of Risks Associated with Our Business

Below is a summary of the principal factors that make an investment in our securities speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below this risk factor summary and should be carefully considered.

- The COVID-19 pandemic continues to adversely impact our business, including our clinical trials, supply chain and business development activities.
- We are a clinical-stage biopharmaceutical company with a limited operating history. We have incurred net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future. We have never generated any revenue from product sales and may never be profitable.
- Our product candidates are in the early stages of development and we have a limited history of conducting clinical trials to test our product candidates in humans.
- Our product candidates are based on novel technologies, which make it difficult to predict the timing, results and cost of product candidate development and likelihood of obtaining regulatory approval.
- Serious adverse events, undesirable side effects or other unexpected properties of our product candidates may be identified during development or after approval, which could lead to the discontinuation of our clinical development programs, refusal by regulatory authorities to approve our product candidates or, if discovered following marketing approval, revocation of marketing authorizations or limitations on the use of our product candidates thereby limiting the commercial potential of such product candidate.
- We rely on third parties to conduct our clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects.
- We face substantial competition, which may result in others discovering, developing or commercializing products more quickly or marketing them more successfully than us.
- We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.
- We are currently party to several in-license agreements under which we acquired rights to use, develop, manufacture and/or commercialize certain of our genetic engineering technologies and resulting product candidates. If we breach our obligations under these agreements, we may be required to pay damages, lose our rights to these technologies or both, which would adversely affect our business and prospects.

- Our collaborators may not devote sufficient resources to the development or commercialization of our product candidates or may otherwise fail in development or commercialization efforts, which could adversely affect our ability to develop or commercialize certain of our product candidates and our financial condition and operating results.
- We will need to obtain substantial additional funding to complete the development and any commercialization of our product candidates. If we are unable to raise this capital when needed, we may be forced to delay, reduce or eliminate our product development programs or other operations.
- If we are unable to obtain and maintain sufficient intellectual property protection for our platform technologies and product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our products may be adversely affected.
- If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates.

Risks Related to Our Limited Operating History, Financial Position and Capital Requirements

**** We are a clinical-stage biopharmaceutical company with a limited operating history. We have incurred net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future. We have never generated any revenue from product sales and may never be profitable.***

We are a clinical-stage biopharmaceutical company with a limited operating history that may make it difficult to evaluate the success of our business to date and to assess our future viability. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, establishing and protecting our intellectual property portfolio, developing our platform technologies, identifying potential product candidates and undertaking research and development and manufacturing activities, including preclinical studies and clinical trials of our product candidates. All of our product candidates are in early development, and none have been approved for commercial sale. We have never generated any revenue from product sales and have incurred net losses each year since we commenced operations. For the six months ended June 30, 2022 and 2021, we have incurred a net loss of $101.1 million and $84.0 million, respectively. As of June 30, 2022, we had an accumulated deficit of $508.0 million. We expect that it will be several years, if ever, before we have a product candidate ready for regulatory approval and commercialization. We expect to incur increasing levels of operating losses over the next several years and for the foreseeable future as we advance our product candidates through clinical development. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

To become and remain profitable, we must develop and eventually commercialize a product or products with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our product candidates, obtaining marketing approval for these product candidates, manufacturing, marketing and selling those products for which we may obtain marketing approval and satisfying any post-marketing requirements. We may never succeed in these activities and, even if we succeed in commercializing one or more of our product candidates, we may never generate revenue that is significant or large enough to achieve profitability. In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis and we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

**** We will need to obtain substantial additional funding to complete the development and any commercialization of our product candidates. If we are unable to raise this capital when needed, we may be forced to delay, reduce or eliminate our product development programs or other operations.***

Since our inception, we have used substantial amounts of cash to fund our operations and expect our expenses to increase substantially during the next few years. The development of biopharmaceutical product candidates is capital intensive. As our product candidates enter and advance through preclinical studies and clinical trials, we will need substantial additional funds to expand our clinical, regulatory, quality and manufacturing capabilities. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to marketing, sales, manufacturing and distribution.

As of June 30, 2022, we had $142.6 million in cash, cash equivalents and short-term investments. Based upon our current operating plan, we believe that our existing cash and cash equivalents, in combination with the upfront payment of $110.0 million to be received pursuant to the Roche Collaboration Agreement and the net proceeds from the underwritten public offering of approximately $75.3 million, will enable us to fund our operations through at least the next 12 months. However, our current cash and

cash equivalents will not be sufficient to fund any of our product candidates through regulatory approval, and we will need to raise substantial additional capital to complete the development and commercialization of our product candidates.

Additional capital may be obtained through equity offerings and/or debt financings, or from other potential sources of liquidity, which may include new collaborations, licensing or other commercial agreements for one or more of our research programs or patent portfolios. Adequate funding, if needed, may not be available to us on acceptable terms, or at all. Our ability to obtain additional funds may be adversely impacted by civil and political unrest in certain countries and regions, potential worsening global economic conditions and the disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the continuing public health concerns regarding the COVID-19 pandemic. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce, or eliminate our research development programs or other operations. If any of these events occur, our ability to achieve our operational goals would be materially and adversely affected. Our future capital requirements and the adequacy of available funds will depend on many factors, including those described in "Risk Factors." Depending on the severity and direct impact of these factors on us, we may be unable to secure additional financing to meet our operating requirements on terms favorable to us, or at all.

We have based these estimates on assumptions that may prove to be incorrect or require adjustment as a result of business decisions, and we could exhaust our available capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- scope, progress and results of our ongoing and planned preclinical studies and clinical trials for our product candidates;
- unanticipated serious safety concerns related to the use of our product candidates;
- timing of licensing payments we may be required to make based on the development of our product candidates;
- the number, and development requirements of other product candidates that we may pursue;
- the timing and outcome of regulatory review of our product candidates;
- changes in laws or regulations applicable to our product candidates, including but not limited to clinical trial requirements for approval;
- our decisions to initiate additional clinical trials, not to initiate any clinical trial or to terminate an existing clinical trial;
- the cost of obtaining raw materials and drug product for clinical trials and commercial supply, which, due to the wide variability in manufacturing costs between autologous and allogeneic product candidates, will also depend on which product candidates progress to future clinical trials;
- whether we decide to partner any of our product candidates with any third parties and the terms of any such partnership or collaboration;
- the cost and timing of establishing and validating our pilot manufacturing facility;
- whether we decide to establish a commercial manufacturing facility for supply of our product candidates; and
- additions or departures of key scientific or management personnel.

Because we do not expect to generate revenue from product sales for many years, if at all, we will need to obtain substantial additional funding in connection with our continuing operations and expected increases in expenses. Until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potentially grants, collaborations, licenses or other similar arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. The impact of the COVID-19 pandemic, as well as changes in interest rates and economic inflation on capital markets may affect the availability, amount and type of financing available to us in the future. On August 13, 2021, we entered into a Controlled Equity Offering^{SM} Sales Agreement, or the Sales Agreement, with Cantor Fitzgerald & Co., or Cantor, to sell shares of common stock, from time to time, through an "at the market offering" program having an aggregate offering price of up to $85.0 million through which Cantor would act as sales agent. There can be no assurance that we will meet the requirements to be able to sell securities pursuant to the Sales Agreement, of if we meet the requirements that we will be able to raise sufficient funds on favorable terms. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

The terms of our loan agreement place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

We have an outstanding term loan in the principal amount of $60.0 million under our loan and security agreement with Oxford Finance LLC, or Oxford. The loan is secured by a lien covering substantially all of our personal property, rights and assets, excluding intellectual property. The loan agreement contains customary affirmative and negative covenants and events of default applicable to us and any subsidiaries. The affirmative covenants include, among others, covenants requiring us (and us to cause our subsidiaries, if any) to maintain governmental approvals, deliver certain financial reports, maintain insurance coverage, keep inventory, if any, in good and marketable condition and protect material intellectual property. The negative covenants include, among others, restrictions on us and our subsidiaries transferring collateral, incurring additional indebtedness, engaging in mergers or acquisitions, paying cash dividends or making other distributions, making investments, creating liens, selling assets and making any payment on subordinated debt, in each case subject to certain exceptions. The restrictive covenants of the loan agreement could cause us to be unable to pursue business opportunities that we or our stockholders may consider beneficial. In addition, among other default triggers, Oxford could declare a default upon the occurrence of any event that it interprets as a material adverse change as defined under the loan agreement. If we default under the loan agreement, Oxford may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Further, if we are liquidated, Oxford's right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. Any declaration by Oxford of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

Risks Related to the Discovery, Development and Regulatory Approval of Our Product Candidates

Our product candidates are in the early stages of development and we have a limited history of conducting clinical trials to test our product candidates in humans.

We are early in our development efforts and most of our operations to date have been limited to developing our platform technologies, establishing manufacturing capabilities and conducting drug discovery and preclinical studies. In November 2021, we made the decision to wind down clinical development of our P-BCMA-101 program, which was the first of our product candidates to have been tested in humans. We dosed the first patient in a Phase 1 clinical trial of P-PSMA-101 in May 2020, and initiated Phase 1 clinical trials for P-BCMA-ALLO1 and P-MUC1C-ALLO1 in late 2021. As a result, we have limited infrastructure, experience conducting clinical trials as a company and regulatory interactions, and cannot be certain that our clinical trials will be completed on time, that our planned clinical trials will be initiated on time, if at all, that our planned development programs would be acceptable to the FDA or other comparable foreign regulatory authorities, or that, if approval is obtained, such product candidates can be successfully commercialized.

Because of the early stage of development of our product candidates, our ability to eventually generate significant revenues from product sales will depend on a number of factors, including:

- successful completion of preclinical studies;
- submission of our INDs or other regulatory applications for our planned clinical trials or future clinical trials and authorizations from regulators to initiate clinical studies;
- successful enrollment in, and completion of, clinical trials and achieving positive results from the trials;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing manufacturing capabilities or arrangements with third-party manufacturers for clinical supply and, if and when approved, for commercial supply;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in combination with others;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- developing and implementing marketing and reimbursement strategies;
- obtaining and maintaining third-party coverage and adequate reimbursement;
- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity for our product candidates;
- the ability to obtain clearance or approval of companion diagnostic tests, if required, on a timely basis, or at all; and
- maintaining a continued acceptable safety profile of any product following approval, if any.

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

Clinical development is a lengthy, expensive and uncertain process. The results of preclinical studies and early clinical trials are not always predictive of future results. Any product candidate that we advance into clinical trials may not achieve favorable results in later clinical trials, if any, or receive marketing approval.

The research and development of drugs and biological products is extremely risky. Only a small percentage of product candidates that enter the development process ever receive marketing approval. Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates in humans. Clinical testing is expensive, can take many years to complete and its outcome is uncertain.

The results of preclinical studies and early clinical trials of our product candidates and other products, even those with the same or similar mechanisms of action, may not be predictive of the results of later-stage clinical trials. In particular, it is not uncommon for product candidates to exhibit unforeseen safety or efficacy issues when tested in humans despite promising results in preclinical animal models. In August 2020, we announced the P-PSMA-101 trial was put on clinical hold to assess a patient death. This clinical hold was lifted in November 2020 with the implementation of protocol amendments intended to increase patient compliance and safety that include modified inclusion and exclusion criteria and frequency of monitoring and laboratory testing. On February 17, 2022, we presented interim results from 14 treated and evaluable patients in our P-PSMA-101 Phase 1 clinical trial. In addition, due primarily to the observation of anti-drug antibodies in some patients in our first clinical trial, P-BCMA-101, we explored additional dosing strategies, such as administering the doses in smaller cycles in the first 30 days and adding rituximab to the preconditioning regimen to potentially suppress any antibody response. If these anti-drug antibodies are neutralizing the product candidate, the activity of P-BCMA-101, or any other product candidate in which anti-drug antibodies neutralize the product candidate, may be limited. To the extent that we choose one of these newer dosing strategies for advancement in any of our clinical trials, it may be on the basis of more limited data as compared to the previously evaluated Phase 1 cohorts. Other than P-BCMA-101 and our current clinical trials, none of our product candidates have ever been tested in humans. We have only recently initiated clinical trials for our first two allogeneic CAR-T product candidates, P-BCMA-ALLO1, and P-MUC1C-ALLO1. While we have applied learnings from our autologous P-BCMA-101 product candidate in our development of P-BCMA-ALLO1, we cannot be certain that these learnings will be applicable to the allogeneic program or that we will not encounter unexpected results dosing P-BCMA-ALLO1 or P-MUC1C-ALLO1 for the first time in humans. Future results of preclinical and clinical testing of our product candidates are also less certain due to the novel and relatively untested nature of our approach to CAR-T and gene therapy development and related platform technologies. In general, clinical trial failure may result from a multitude of factors including flaws in study design, dose selection, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits. As such, failure in clinical trials can occur at any stage of testing. A number of companies in the biopharmaceutical industry have suffered setbacks in the advancement of clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials.

If the results of our clinical trials are inconclusive or if there are safety concerns or adverse events associated with our product candidates, we may:

- incur unplanned costs;
- be delayed in or prevented from obtaining marketing approval for our product candidates;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings including boxed warnings;
- be subject to changes in the way the product is administered;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw their approval of the product or impose restrictions on its distribution in the form of a modified Risk Evaluation and Mitigation Strategy, or REMS;
- be subject to the addition of labeling statements, such as warnings or contraindications;
- be sued; or
- experience damage to our reputation.

Treatment with our oncology product candidates involves chemotherapy and myeloablative treatments, which can cause side effects or adverse events that are unrelated to our product candidate but may still impact the success of our clinical trials. Additionally, our product candidates could potentially cause other adverse events. The inclusion of critically ill patients in our clinical trials may

result in deaths or other adverse medical events due to other therapies or medications that such patients may be using. As described above, any of these events could prevent us from obtaining regulatory approval or achieving or maintaining market acceptance of our product candidates and impair our ability to commercialize our products. Because all of our product candidates are derived from our platform technologies, a clinical failure of one of our product candidates may also increase the actual or perceived likelihood that our other product candidates will experience similar failures.

We may encounter substantial delays in our clinical trials.

We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. For example, we cannot begin our planned Phase 1 clinical trials for our liver directed gene therapy candidates until we or our collaborators complete certain preclinical development and submit and receive authorization to proceed under INDs. While we announced FDA clearance for our IND for P-BCMA-ALLO1 in August 2021 and our IND for P-MUC1C-ALLO1 in December 2021, we are dependent on clinical sites to complete startup activities and enroll patients. We announced in August 2020 our P-PSMA-101 trial was put on clinical hold to assess a patient death. In November 2020 we announced that the FDA had lifted the clinical hold based upon our investigation of the event and proposed protocol amendments intended to increase patient compliance and safety. While we have resumed the trial, the clinical hold will delay the ultimate completion of the trial and we cannot guarantee that after resuming the trial, we will not observe additional patient deaths or encounter other events that cause the P-PSMA-101 trial be suspended or terminated. Finally, the COVID-19 pandemic has impacted clinical trials broadly, including our own, with some sites pausing enrollment and we have experienced a delay in manufacturing at times due to potential exposure. These impacts have caused us to reevaluate the expected timing of clinical milestones and we have and continue to experience delays in site initiation and patient enrollment, and could also experience delays in the manufacture of our product candidates for clinical testing and other difficulties in starting or completing our clinical trials. Other events that may prevent successful or timely completion of clinical development include:

- delays in reaching a consensus with regulatory agencies on trial design;
- delays in reaching agreement on acceptable terms with prospective clinical research organizations, or 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;
- delays in obtaining required institutional review board, or IRB, approval at each clinical trial site;
- delays in recruiting suitable patients to participate in our clinical trials;
- imposition of a clinical hold by regulatory agencies, after an inspection of our clinical trial operations or study sites;
- failure by our CROs, other third parties or us to adhere to the trial protocol or the FDA's good clinical practices, or GCPs, or applicable regulatory guidelines in other countries;
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other comparable foreign regulatory authorities for violations of applicable regulatory requirements;
- delays in the testing, validation, manufacturing and delivery of our product candidates to the treatment sites, including due to a facility manufacturing any of our product candidates or any of their components being ordered by the FDA or comparable foreign regulatory authorities to temporarily or permanently shut down due to violations of current good manufacturing practices, or cGMPs, regulations or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;
- delays in having patients complete participation in a study or return for post-treatment follow-up;
- clinical trial sites or patients dropping out of a study;
- discovering that product candidates have unforeseen safety issues, undesirable side effects or other unexpected characteristics;
- to the extent that we conduct clinical trials in foreign countries, the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries;
- receiving untimely or unfavorable feedback from applicable regulatory authorities regarding the trial or requests from regulatory authorities to modify the design of a trial;
- suspensions or terminations by us, the IRBs of the institutions at which such trials are being conducted, by the Data Safety Monitoring Board, for such trial or by regulatory authorities due to a number of factors, including those described above;
- lack of adequate funding; or

- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to raise capital, generate revenues from product sales and enter into or maintain collaboration arrangements. For example, under certain of our manufacturing agreements for our product candidates we pay a fixed price per month for up to a specified number of manufacturing runs and certain clinical trial services agreements are based on fees that do not vary based on patient enrollment. Therefore, if enrollment in a clinical trial is slowed, certain of our expenses related to the trial would not decrease and therefore the overall costs to complete the trial would increase. In addition, if we make manufacturing changes to our product candidates, we may need to conduct additional studies to bridge our modified product candidates to earlier versions. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

Our product candidates are based on novel technologies, which make it difficult to predict the timing, results and cost of product candidate development and likelihood of obtaining regulatory approval.

We have concentrated our research and development efforts on product candidates using our platform technologies, and our future success depends on the successful development of this approach. CAR-T and gene editing in general are newly-emerging fields and our approaches in particular have not been extensively tested over any significant period of time. In particular, while we believe that CAR-T products with higher percentages of T_{SCM} cells may be capable of overcoming certain challenges faced by early-generation CAR-T products, we cannot be certain that increasing the percentage of these cells will result in the intended benefits or will not result in unforeseen negative consequences over time, including due to the potential long-term persistence of the modified cells in the body. We have not yet succeeded and may not succeed in demonstrating efficacy and safety for any product candidates based on our platform technologies in clinical trials or in obtaining marketing approval thereafter, and use of our platform technologies may not ever result in marketable products. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners or establishing our own commercial manufacturing capabilities, which may prevent us from completing our clinical trials or commercializing any products on a timely or profitable basis, if at all.

In addition, the clinical trial requirements of the FDA, the European Medicines Agency, or EMA, and other regulatory agencies and the criteria these regulators use to determine 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 novel product candidates such as ours can be more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates. While CAR-T and gene therapy products have made progress in recent years, only a small number of products have been approved in the United States or other markets, which makes it difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our product candidates.

In addition, the gene-editing industry is rapidly developing, and our competitors may introduce new technologies that render our technologies obsolete or less attractive. New technology could emerge at any point in the development cycle of our product candidates. As competitors use or develop alternative technologies, any failures of such technologies could adversely impact our programs. For example, some studies have suggested that gene editing using the CRISPR-Cas9 method may increase the risk that the edited cells themselves become cancerous, and in October 2021, discovery of a chromosomal abnormality of unknown clinical significance resulted in a full clinical hold on the programs of one of our competitors utilizing the TALEN method. Regardless of our belief that our non-viral Cas-CLOVER approach to gene editing may avoid some of the issues identified in these studies, it is possible that our approach will be associated with similar risks or that issues encountered with other gene editing techniques will create a negative perception of or increase scrutiny for our technologies and product candidates.

Regulatory requirements governing products created with gene 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 is substantial, and sometimes uncoordinated, overlap in those responsible for regulation of gene therapy products and other products created with gene editing technology. For example, under the National Institutes of Health, or NIH, Guidelines for Research Involving Recombinant DNA Molecules, or NIH Guidelines, supervision of human gene transfer trials includes evaluation and assessment by an institutional biosafety committee, or 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. Even though we may not be required to submit a protocol for our product candidates through the NIH for review, we will still be subject to significant

regulatory oversight by the FDA, and in addition to the government regulators, the applicable IBC and IRB of each institution at which we conduct clinical trials of our product candidates, or a central IRB if appropriate, would need to review and approve the proposed clinical trial.

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 gene editing, may cause the FDA and other regulatory bodies to revise the requirements for approval of any product candidates we may develop or limit the use of products utilizing gene 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.

We are also developing allogeneic CAR-T product candidates that are engineered from healthy donor T cells and are intended for use in any patient with certain cancers. Allogeneic versions of CAR-T product candidates is an unproven field of development and is subject to particular risks that are difficult to quantify, including understanding and addressing variability in the quality of a donor's T cells and the patient's potential immune reaction to the foreign donor cells, which could ultimately affect safety, efficacy and our ability to produce product in a reliable and consistent manner. For example, in response to FDA feedback to our IND for P-BCMA-ALLO1, we were required to update certain assay release criteria unique to an allogeneic product candidate. While implementation of this update has not yet impacted our clinical timelines, there can be no assurance that it, or similar regulatory requirements would not do so in the future, and any such delays could materially and adversely affect our business, financial condition, results of operations and future growth prospects.

Serious adverse events, undesirable side effects or other unexpected properties of our product candidates may be identified during development or after approval, which could lead to the discontinuation of our clinical development programs, refusal by regulatory authorities to approve our product candidates or, if discovered following marketing approval, revocation of marketing authorizations or limitations on the use of our product candidates thereby limiting the commercial potential of such product candidate.

To date, we have only tested our product candidates in a limited number of patients with cancer and the majority of these clinical trial participants have only been observed for a limited period of time after dosing. As we continue developing our product candidates and initiate clinical trials of our additional product candidates, serious adverse events, or SAEs, undesirable side effects, relapse of disease or unexpected characteristics may emerge causing us to abandon these product candidates or limit their development to more narrow uses or subpopulations in which the SAEs or undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective or in which efficacy is more pronounced or durable. For example, a significant risk observed in CAR-T product clinical trials is the development of CRS which in some instances resulted in neurotoxicity and patient deaths. While we have observed relatively limited instances of CRS or neurotoxicity in clinical trials of P-BCMA-101 and P-PSMA-101, we may observe greater rates of these or other adverse events in our other CAR-T programs. Should we observe additional or more severe cases of CRS in our clinical trials or identify other undesirable side effects or other unexpected findings depending on their severity, our trials could be delayed or even stopped and our development programs may be halted entirely. In August 2020, we announced our P-PSMA-101 trial was placed on clinical hold to evaluate the death of a patient, which may have been related to treatment with P-PSMA-101. In November 2020 we announced that the FDA had lifted the clinical hold based upon our investigation of the event and proposed protocol amendments intended to increase patient compliance and safety, and we have resumed the trial and we reported interim results on the first 14 patients in February 2022. Despite the clinical hold being lifted, we could observe similar patient deaths or other adverse events that require that the P-PSMA-101 trial be suspended or terminated, which could represent a substantial setback to the program.

Even if our product candidates initially show promise in early clinical trials, the side effects of biological products are frequently only detectable after they are tested in larger, longer and more extensive clinical trials or, in some cases, after they are made available to patients on a commercial scale after approval. Sometimes, it can be difficult to determine if the serious adverse or unexpected side effects were caused by the product candidate or another factor, especially in oncology subjects who may suffer from other medical conditions and be taking other medications. If serious adverse or unexpected side effects are identified during development or after approval and are determined to be attributed to our product candidate, we may be required to develop 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. Product-related side effects could also result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

In addition, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- 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 clinical trials;
- the product may become less competitive;
- we may decide to remove the product from the marketplace; and
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties.

Interim, topline and preliminary data from our clinical trials may change as more patient data become available, and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary, interim or topline data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change as patient enrollment and treatment continues and more patient data become available. Adverse differences between previous preliminary or interim data and future interim or final data could significantly harm our business prospects. We may also announce topline data following the completion of a preclinical study or clinical trial, which may be subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim, topline and preliminary data should be viewed with caution until the final data are available.

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 to be material or otherwise appropriate information to include in our disclosure.

We may not ultimately receive or realize the potential benefits of orphan drug designation for any of our product candidates.

We may seek orphan drug designation for certain of our product candidates. The FDA grants orphan designation to drugs that are intended to treat rare diseases with fewer than 200,000 patients in the United States or that affect more than 200,000 persons but where there is no reasonable expectation to recover the costs of developing and marketing a treatment drug in the United States. While we previously received orphan drug designation for P-BCMA-101 for the treatment of relapsed/refractory multiple myeloma, we may not receive this designation for P-BCMA-ALLO1 or any other product candidate in the future. 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 application 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. However, orphan drug designation neither shortens the development time nor regulatory review time of a product candidate nor gives the candidate any advantage in the regulatory review or approval process.

In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity for the orphan patient population. Exclusive marketing rights in the United States may also be unavailable 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. Even if we obtain orphan drug designation, we may not be the first to obtain marketing approval for any

particular orphan indication due to the uncertainties associated with developing pharmaceutical products. Further, even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition.

We may seek Regenerative Medicine Advanced Therapy, or RMAT, designation for certain of our product candidates; however, even if granted, such designations may not lead to a faster development or regulatory review or approval process and do not increase the likelihood that our product candidates will receive marketing approval.

In 2017, the FDA established the RMAT designation as part of its implementation of the 21st Century Cures Act. An investigational drug is eligible for RMAT designation if: (1) it meets the definition of a regenerative medicine therapy, 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 disease or condition; and (3) preliminary clinical evidence indicates that the investigational drug has the potential to address unmet medical needs for such disease or condition. While we previously received RMAT designation for P-BCMA-101 for the treatment of multiple myeloma, we may not receive this designation for any other product candidate in the future. RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate, and eligibility for rolling review of BLAs and priority review. Product candidates 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 of clinical trials, as appropriate. RMAT-designated product candidates that receive accelerated approval may, as determined by the FDA, 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.

RMAT designation does not change the standards for product approval, and there is no assurance that such designation or eligibility for such designation will result in expedited review or approval or that the approved indication will not be narrower than the indication covered by the RMAT designation. Additionally, RMAT designation can be revoked if the criteria for eligibility cease to be met as clinical data emerges.

Our product candidates must meet extensive regulatory requirements before they can be commercialized and any regulatory approval may contain limitations or conditions that require substantial additional development expenses or limit our ability to successfully commercialize the product.

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of our product candidates are subject to extensive regulation by the FDA in the United States and by comparable foreign regulatory authorities in foreign markets. In the United States, we are not permitted to market our product candidates until we receive regulatory approval from the FDA. The process of obtaining regulatory approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications and patient population. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed.

To date, we have not submitted a BLA or other marketing authorization application to the FDA or similar drug approval submissions to comparable foreign regulatory authorities for any product candidate. Accelerated approval requires the data to indicate the drug candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or an effect on a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. In particular, because the FDA has already approved therapies for certain of the indications our product candidates are designed to treat, and because additional drugs may be approved for these indications while we are developing our product candidates, it is difficult to predict whether accelerated approval will be possible for our product candidates at the time we expect to submit a BLA.

Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we or our potential future collaborators must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses. Even if we believe the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and comparable foreign regulatory authorities. In particular, because we are seeking to identify and develop product candidates using new technologies, there is heightened risk that the FDA or other regulatory authorities may impose additional requirements prior to granting marketing approval, including enhanced safety studies or monitoring. Furthermore, as more

product candidates within a particular class of products proceed through clinical development to regulatory review and approval, the amount and type of clinical data that may be required by regulatory authorities may increase or change.

The FDA or comparable foreign regulatory authorities can delay, limit or deny approval of a product candidate for many reasons, including:

- such authorities may disagree with the design or implementation of our clinical trials;
- negative or ambiguous results from our clinical trials or results may not meet the level of statistical significance required by the FDA or comparable foreign regulatory agencies for approval;
- serious and unexpected product-related side effects may be experienced by participants in our clinical trials or by individuals using biological products similar to our product candidates;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- such authorities may not accept clinical data from trials which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the United States;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- such authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- such authorities may not agree that the data collected from clinical trials of our product candidates are acceptable or sufficient to support the submission of an application for regulatory approval or other submissions or to obtain regulatory approval in the United States or elsewhere, including due to clinical trial issues encountered as a result of COVID-19 pandemic, and such authorities may impose requirements for additional preclinical studies or clinical trials;
- such authorities may disagree regarding the formulation, labeling and/or the specifications of our product candidates;
- approval may be granted only for indications that are significantly more limited than what we apply for and/or with other significant restrictions on distribution and use;
- such authorities may fail to approve any required companion diagnostics to be used with our product candidates;
- such authorities may find deficiencies in the manufacturing processes or facilities of our third-party manufacturers with which we or any of our potential future collaborators contract for clinical and commercial supplies; or
- the approval policies or regulations of such authorities may significantly change in a manner rendering our or any of our potential future collaborators' clinical data insufficient for approval.

With respect to foreign markets, approval procedures vary among countries and, in addition to the foregoing risks, may involve additional product testing, administrative review periods and agreements with pricing authorities. In addition, events raising questions about the safety of certain marketed pharmaceuticals may result in increased cautiousness by the FDA and comparable foreign regulatory authorities in reviewing new products based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals.

Even if we eventually complete clinical trials and receive approval to commercialize our product candidates, the FDA or comparable foreign regulatory authority may grant approval contingent on the performance of costly additional clinical trials, including Phase 4 clinical trials, and/or the implementation of a REMS. The FDA or the comparable foreign regulatory authority also may approve a product candidate for a more limited indication or patient population than we originally requested or may not approve the labeling that we believe is necessary or desirable for the successful commercialization of a product. Manufacturers of our products and manufacturers' facilities are also required to comply with cGMP regulations, which include requirements related to quality control and quality assurance, as well as the corresponding maintenance of records and documentation. Further, regulatory authorities must approve these manufacturing facilities before they can be used to manufacture our products, and these facilities are subject to continual review and periodic inspections by the FDA and other comparable foreign regulatory authorities for compliance with cGMP regulations.

Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of that product candidate and would materially and adversely impact our business and prospects.

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

If the FDA, EMA or any other comparable regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration requirements and continued compliance with cGMPs and GCP, for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary product recalls;
- fines, untitled or warning letters or holds on clinical trials;
- refusal by the FDA, the EMA or any other comparable regulatory authority to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

Moreover, if any of our product candidates are approved, our product labeling, advertising and promotion will be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about biopharmaceutical 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.

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 our product candidates, and harm our business, financial condition and results of operations.

In addition, the policies of the FDA, the EMA and other comparable regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements, or if we 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, or 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 agency 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 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 global COVID-19 pandemic, the FDA postponed most foreign and domestic inspections of manufacturing facilities and products for several months during 2020 and only resumed them on a risk-based basis, incorporating remote monitoring methods as well. 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 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.

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

Because we have limited financial and managerial resources, we must prioritize our research programs and will need to focus our discovery and development on select product candidates and indications. Correctly prioritizing our research and development activities is particularly important for us due to the breadth of potential product candidates and indications that we believe could be pursued using our platform technologies. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may also relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

We may not be successful in our efforts to identify or discover additional product candidates in the future.

Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

- our inability to design such product candidates with the properties that we desire; or
- potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance.

Research programs to identify new product candidates require substantial technical, financial and human resources. If we are unable to identify suitable additional candidates for preclinical and clinical development, our opportunities to successfully develop and commercialize therapeutic products will be limited.

Risks Related to Manufacturing, Commercialization and Reliance on Third Parties

We rely on third parties to conduct our clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects.

We do not have the ability to conduct all aspects of our preclinical testing or clinical trials ourselves. As a result, we are and expect to remain dependent on third parties to conduct our ongoing clinical trials and any future clinical trials of our product candidates. Specifically, CROs, clinical investigators, and consultants play a significant role in the conduct of these trials and the subsequent collection and analysis of data. However, we will not be able to control all aspects of their activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area, and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical trial investigators and clinical trial sites. If we or any of our CROs or clinical trial sites fail to comply with applicable GCP requirements, the data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to stop and/or repeat clinical trials, which would delay the marketing approval process.

There is no guarantee that any such CROs, clinical trial investigators or other third parties on which we rely will devote adequate time and resources to our development activities or perform as contractually required. These risks are heightened as a result of the efforts of government agencies and the CROs themselves to limit the spread of COVID-19, including quarantines and shelter-in-place orders. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, otherwise performs in a substandard manner, or terminates its engagement with us, the timelines for our development programs may be extended or delayed or our development activities may be suspended or terminated. If any of our clinical trial sites terminates for any reason, we may experience the loss of follow-up information on subjects enrolled in such clinical trials unless we

are able to transfer those subjects to another qualified clinical trial site, which may be difficult or impossible. In addition, clinical trial investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA or any comparable foreign regulatory authority concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any marketing application we submit by the FDA or any comparable foreign regulatory authority. Any such delay or rejection could prevent us from commercializing our product candidates.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our products.

We or the third parties on which we rely for the manufacturing and supply of certain of our product candidates for use in preclinical testing and clinical trials, may not be able to establish or maintain supply of our product candidates that is of satisfactory quality and quantity.

We produce in our laboratory relatively small quantities of product for evaluation in our research programs. We rely on third parties for the manufacture of certain of our product candidates for preclinical and clinical testing and may continue to rely on such third parties for commercial manufacture if any of our product candidates are approved. We have a pilot manufacturing facility which we are using to develop and manufacture preclinical and clinical material for clinical trials for certain product candidates. We are initially using the facility for the GMP manufacturing of our P-MUC1C-ALLO1 program, however we may encounter delays, quality or other issues as we use our pilot manufacturing facility for clinical supply. Even though the pilot manufacturing facility is validated and qualified, we expect that we will continue to rely on third parties for various manufacturing needs. We currently have limited manufacturing arrangements and expect that each of our product candidates will only be covered by single source suppliers for the foreseeable future. This reliance increases the risk that we will not have sufficient quantities of our product candidates or products, if approved, or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

Furthermore, all entities involved in the preparation of therapeutics for clinical trials or commercial sale, including our existing contract manufacturers for our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in clinical trials must be manufactured in accordance with cGMP requirements. These regulations govern manufacturing processes and procedures, including record keeping, and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants, or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of a BLA on a timely basis and must adhere to the FDA's Good Laboratory Practice regulations and cGMP regulations enforced by the FDA through its facilities inspection program. Comparable foreign regulatory authorities may require compliance with similar requirements. Our facilities and quality systems, and those of our third-party contract manufacturers, must pass a pre-approval inspection for compliance with the applicable regulations as a condition of marketing approval of our product candidates. We do not control the manufacturing activities of, and are completely dependent on, our contract manufacturers for compliance with cGMP regulations.

In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, including due to the impact of the COVID-19 pandemic, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third-party, which we may not be able to do on commercially reasonable terms, if at all. In particular, any replacement of our manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such skills or technology to another third-party and a feasible alternative may not exist. In addition, certain of our product candidates and our own proprietary methods have never been produced or implemented outside of our company, and we may therefore experience delays to our development programs if and when we attempt to establish new third-party manufacturing arrangements for these product candidates or methods. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third-party manufacture our product candidates. If we are required to or voluntarily change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that

comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget.

Our or a third-party's failure to execute on our manufacturing requirements, do so on commercially reasonable terms and comply with cGMP could adversely affect our business in a number of ways, including:

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

Manufacturing genetically engineered products is complex and we or our third-party manufacturers may encounter difficulties in production. If we or any of our third-party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or prevented.

Manufacturing genetically engineered products is complex and may require the use of innovative technologies to handle living cells. Manufacturing these products requires facilities specifically designed for and validated for this purpose and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. When changes are made to the manufacturing process, we may be required to provide preclinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes. If microbial, viral or other contaminations are discovered at manufacturing facilities, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business. The use of biologically derived ingredients can also lead to allegations of harm, including infections or allergic reactions, or closure of product facilities due to possible contamination.

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

Changes in methods of product candidate manufacturing may result in additional costs or delays.

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

Any approved products may fail to achieve the degree of market acceptance by physicians, patients, hospitals, cancer treatment centers, healthcare payors and others in the medical community necessary for commercial success.

If any of our product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. For example, current cancer treatments like chemotherapy and radiation therapy are well established in the medical community, and physicians may continue to rely on these

treatments. Most of our product candidates target mechanisms for which there are limited or no currently approved products, which may result in slower adoption by physicians, patients and payors. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenue and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- efficacy and potential advantages compared to alternative treatments;
- our ability to offer our products for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the availability of coverage and adequate reimbursement from third party payors;
- the strength of marketing and distribution support; and
- the prevalence and severity of any side effects.

We may not be able to successfully commercialize our product candidates due to unfavorable pricing regulations or third-party coverage and reimbursement policies, which could make it difficult for us to sell our product candidates profitably.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time-consuming and costly process, with uncertain results, that could require us to provide supporting scientific, clinical and cost effectiveness data for the use of our products to the payor. There may be significant delays in obtaining such coverage and reimbursement for newly approved products, and coverage may not be available, or may be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a product will be paid for in all cases or at a rate that covers our costs, including research, development, intellectual property, manufacture, sale and distribution expenses. Interim reimbursement levels for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors, by any future laws limiting drug prices and by any future relaxation of laws that presently restrict imports of product from countries where they may be sold at lower prices than in the United States.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, there is no uniform policy among third-party payors for coverage and reimbursement. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting reimbursement policies, but also have their own methods and approval process apart from Medicare coverage and reimbursement determinations. Therefore, one third-party payor’s determination to provide coverage for a product does not assure that other payors will also provide coverage for the product.

Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor’s determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

We cannot be sure that reimbursement will be available for any product that we commercialize and, if coverage and reimbursement are available, what the level of reimbursement will be. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Reimbursement may impact the demand for, and the price of, any product for which we obtain marketing approval. Assuming we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their

conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with those medications. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of our products. Therefore, coverage and adequate reimbursement is critical to a new product's acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new products when more established or lower cost therapeutic alternatives are already available or subsequently become available.

For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself may or may not be available. Instead, the hospital or administering physician may be reimbursed only for providing the treatment or procedure in which our product is used. Further, from time to time, the Centers for Medicare & Medicaid Services, or CMS, revises the reimbursement systems used to reimburse health care providers, including the Medicare Physician Fee Schedule and Hospital Outpatient Prospective Payment System, which may result in reduced Medicare payments.

We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription medicines, medical devices and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the successful commercialization of new products. Further, the adoption and implementation of any future governmental cost containment or other health reform initiative may result in additional downward pressure on the price that we may receive for any approved product.

Additionally, we or collaborators may develop companion diagnostic tests for use with our product candidates. We, or our collaborators, will be required to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement we may seek for our product candidates. While we have not yet developed any companion diagnostic tests for our product candidates, if we do, there is significant uncertainty regarding our ability to obtain coverage and adequate reimbursement for the same reasons applicable to our product candidates.

Outside of the United States, many countries require approval of the sale price of a product before it can be marketed, and the pricing review period only begins after marketing or product licensing approval is granted. To obtain reimbursement or pricing approval in some of these countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue, if any, we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if such product candidates obtain marketing approval.

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

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the Affordable Care Act, signed into law on March 23, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA 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 from the date on which the reference product was first licensed. 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.

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

If any approved products are subject to biosimilar competition sooner than we expect, we will face significant pricing pressure and our commercial opportunity will be limited.

If the market opportunities for any of our product candidates are smaller than we believe they are, our revenue may be adversely affected, and our business may suffer.

We are focused initially on the development of treatments for cancer. Our projections of addressable patient populations that have the potential to benefit from treatment with our product candidates are based on estimates. If any of our estimates are inaccurate, the market opportunities for any of our product candidates could be significantly diminished and have an adverse material impact on our business.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on third parties to research and develop and to manufacture our product candidates, we must share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's independent discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. For example, any academic institution that we may collaborate with will likely expect to be granted rights to publish data arising out of such collaboration and any joint research and development programs may require us to share trade secrets under the terms of our research and development or similar agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

If any of our product candidates are approved for marketing and commercialization and we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market our product candidates, we will be unable to successfully commercialize our product candidates if and when they are approved.

We have no sales, marketing or distribution capabilities or experience. To achieve commercial success for any approved product for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization, which would be expensive and time consuming, or outsource these functions to other third parties. In the future, we may choose to build a focused sales and marketing infrastructure to sell, or participate in sales activities with our collaborators for, some of our product candidates if and when they are approved.

There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize future products on our own include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or educate an adequate numbers of physicians regarding the benefits of any product, once approved;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product portfolios; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenue or the profitability of these product revenue to us are likely to be lower than if we were to market and sell any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our product

candidates or may be unable to do so on terms that are favorable to us. In entering into third-party marketing or distribution arrangements, any revenue we receive will depend upon the efforts of the third parties and we cannot assure you that such third parties will establish adequate sales and distribution capabilities or devote the necessary resources and attention to sell and market any future products effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

Even if we obtain FDA approval of any of our product candidates, we may never obtain approval or commercialize such products outside of the United States, which would limit our ability to realize their full market potential.

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our ability to realize the full market potential of our products will be harmed.

Risks Related to Our In-Licenses and Other Strategic Agreements

We are currently party to several in-license agreements under which we acquired rights to use, develop, manufacture and/or commercialize certain of our platform technologies and resulting product candidates. If we breach our obligations under these agreements, we may be required to pay damages, lose our rights to these technologies or both, which would adversely affect our business and prospects.

We rely, in part, on license and other strategic agreements, which subject us to various obligations, including diligence obligations with respect to development and commercialization activities, payment obligations for achievement of certain milestones and royalties on product sales, negative covenants and other material obligations. For example, with respect to P-PSMA-101, we have licensed Centyrin binders under an agreement with Janssen Biotech Inc., or Janssen, with respect to P-BCMA-ALLO1, P-CD19CD20-ALLO1 and P-PSMA-ALLO1, we have licensed heavy-chain-only binders under agreements with TeneoBio, Inc. (a subsidiary of Amgen Inc.), or TeneoBio, with respect to P-MUC1C-ALLO1, we have licensed a binder under our agreement with Xyone Therapeutics, Inc. (as successor-in-interest to Genus Oncology, LLC), or Xyone, with respect to our additional dual CAR programs and other allogeneic preclinical programs we have licensed and may continue to license binders under our agreements with TeneoBio, and with respect to our Cas-CLOVER gene editing technology, which we use in the manufacture of P-BCMA-ALLO1, P-MUC1C-ALLO1, P-CD19CD20-ALLO1 and future allogeneic products, we have licensed certain intellectual property under an agreement with Helmholtz-Zentrum M✔nchen—Deutsches Forschungszentrum f✔r Gesundheit und Umwelt GmbH. If we fail to comply with the obligations under our license agreements, including as a result of COVID-19 impacting our operations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and our licensors may have the right to terminate the license. If our license agreements are terminated, we may not be able to develop, manufacture, market or sell the products covered by our agreements and those being tested or approved in combination with such products. Such an occurrence could materially adversely affect the value of the product candidates being developed under any such agreement.

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

Our business also would suffer if any current or future licensors fail to abide by the terms of the license, if the licensors fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor’s rights.

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

If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant research programs or product candidates and our business, financial condition, results of operations and prospects could suffer.

**** We may not realize the benefits of any acquisitions, in-license or strategic alliances that we enter into or fail to capitalize on programs that may present a greater commercial opportunity or for which there is a greater likelihood of success.***

Our business depends upon our ability to identify, develop and commercialize research programs or product candidates. A key element of our business strategy is to discover and develop additional programs based upon our core proprietary platforms, including our non-viral piggyBac DNA Delivery System, Cas-CLOVER Site-specific Gene Editing System and nanoparticle- and AAV-based gene delivery technologies. In addition to internal research and development efforts, we are also seeking to do so through strategic collaborations, such as our collaborations with Roche and Takeda, and may also explore additional strategic collaborations for the discovery of new programs. We have also entered into in-license agreements with multiple licensors and in the future may seek to enter into acquisitions or additional licensing arrangements with third parties that we believe will complement or augment our existing technologies and product candidates.

These transactions can entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention in order to manage a collaboration or develop acquired products, product candidates or technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected development or manufacturing costs, higher than expected personnel and other resource commitments, higher than expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business. As a result, if we enter into acquisition or in-license agreements or strategic partnerships, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, or if there are materially adverse impacts on our or the counterparty's operations resulting from COVID-19, which could delay our timelines or otherwise adversely affect our business. Further, because we have limited resources, we must choose to pursue and fund the development of specific types of treatment, or treatment for a specific type of cancer, and we may forego or delay pursuit of opportunities with certain programs or products or for indications that later prove to have greater commercial potential. Our estimates regarding the potential market for our program could be inaccurate, and if we do not accurately evaluate the commercial potential for a particular program, we may relinquish valuable rights to that program through a strategic collaboration, licensing or other arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such program. Alternatively, we may allocate internal resources to a program in which it would have been more advantageous to enter into a partnering arrangement. If any of these events occur, we may be forced to abandon or delay our development efforts with respect to a particular product candidate or fail to develop a potentially successful program.

**** Our collaborators may not devote sufficient resources to the development or commercialization of our product candidates or may otherwise fail in development or commercialization efforts, which could adversely affect our ability to develop or commercialize certain of our product candidates and our financial condition and operating results.***

We have, with respect to our collaboration with Roche and Takeda, and will likely have, with respect to any additional collaboration arrangements with any third parties, limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. For example, while we expect to collaborate with Takeda on the development of up to six *in vivo* gene therapy programs, only two such programs have been designated by Takeda and we cannot guarantee that Takeda will elect to pursue development of additional gene therapy programs under the collaboration. Similarly, while we expect to collaborate with Roche on the development of up to ten allogeneic CAR-T cell therapy programs and have granted to Roche an option to acquire licenses under certain of our intellectual property to develop, manufacture and commercialize products for up to three solid tumor targets, only two such programs have been designated by Roche and we cannot guarantee that Roche will elect to pursue development of additional cell therapy programs under the Roche Collaboration Agreement.. In each case, a decision by Roche or Takeda to pursue less than the maximum number of targets or programs available for collaboration under their respective collaboration agreements will limit the potential payments we may receive under such collaboration agreements, delay our development timelines or otherwise adversely affect our business. In general, 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 and otherwise to comply with their contractual obligations.

Any of our existing or future collaborations may not ultimately be successful, which could have a negative impact on our business, results of operations, financial condition and growth prospects. In addition, the terms of any such collaboration or other arrangement may not prove to be favorable to us or may not be perceived as favorable, which may negatively impact the trading price of our common stock. In some cases, we may be responsible for continuing development or manufacture of a product or product candidate or research program under collaboration and the payment we receive from our partner may be insufficient to cover the cost of this development or manufacture. For example, under the Takeda Collaboration Agreement, we are obligated to perform certain platform development activities at our own cost. In addition, under the Roche Collaboration Agreement, while Roche is obligated to reimburse us for a specified percentage of certain costs incurred in performance of development activities relating to P-BCMA-ALLO1 and P-CD19CD20-ALLO1, we will be responsible for the balance and the amount Roche is obligated to reimburse us is subject to a maximum cap.

Conflicts may arise between us and our collaborators, such as conflicts concerning the interpretation of clinical data, the achievement of milestones, the division of development responsibilities or expenses, development plans, the interpretation of financial provisions, or the ownership of intellectual property developed during the collaboration. If any such conflicts arise, a collaborator could act in its own self-interest, which may be adverse to our best interests. Any such disagreement between us and a collaborator could delay or prevent the development or commercialization of our product candidates.

Further, we are subject to the following additional risks associated with our current and any future collaborations with third parties, the occurrence of which could cause our collaboration arrangements to fail:

- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may enter into arrangements with our competitors and may prioritize their own programs or those of third parties, over ours;
- collaborators may fail in their development or commercialization efforts with our product candidate, in which event the development and commercialization of such product candidate could be delayed or terminated;
- collaborators may not always be cooperative or responsive in providing their services in clinical trials, may delay clinical trials, insufficiently fund a clinical trial program, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- collaborators may fail to successfully design or implement clinical trials and may collect and publish clinical trial data that are inconsistent with, or contradictory to, our clinical trial results;
- collaborators may not properly enforce, maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- collaborators may own or co-own intellectual property covering our programs or future products that results from our collaboration with them, and in such cases, we would not have the exclusive right over such intellectual property;
- collaborators may deviate from established guidelines, instructions, or best practices for product handling and storage, which may compromise the safety, purity, potency, and effectiveness of our products and potentially result in the occurrence of serious adverse events in patients using our products;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates;
- we could experience reductions in the payments we believe are due to us pursuant to the applicable collaboration arrangement;
- collaborators could take actions inside or outside our collaboration that could negatively impact our rights or benefits under the applicable collaboration; or
- our collaborators may be unwilling to keep us informed regarding the progress of their development and commercialization activities or to permit public disclosure of their progress.

We may wish to form additional collaborations in the future with respect to our product candidates, but may not be able to do so or to realize the potential benefits of such transactions, which may cause us to alter or delay our development and commercialization plans.

The development and potential commercialization of our product candidates will require substantial additional capital to fund expenses. We may, in the future, decide to collaborate with other biopharmaceutical companies for the development and potential commercialization of certain product candidates, including in territories outside the United States or for certain indications. We will face significant competition in seeking appropriate collaborators. We may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. Third party collaborations generally require us to relinquish some or all of the control over the future success of the applicable product candidates to the third-party. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of our technologies, product candidates and market opportunities. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under any license agreements from entering into agreements on certain terms or at all with potential collaborators.

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

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

Risks Related to Our Industry and Business Operations

The COVID-19 pandemic continues to adversely impact our business, including our clinical trials, supply chain and business development activities.

In March 2020, the World Health Organization made the assessment that a novel strain of coronavirus, SARS-CoV-2, a novel strain of coronavirus, commonly referred to as COVID-19 had become a global pandemic. In March 2020, the United States declared the COVID-19 pandemic a national emergency and many states and municipalities in the Unites States have taken aggressive actions to reduce the spread and ameliorate the impact of the disease, including limiting non-essential gatherings of people and non-essential travel, ordering certain businesses and government agencies to cease non-essential operations at physical locations and issuing "shelter-in-place" orders which direct individuals to shelter at their places of residence (subject to limited exceptions) and have also implemented multi-step policies with the goal of re-opening such states and municipalities. As a result of these actions and in an effort to ensure the safety of employees during the pandemic, a majority of our employees are at least partially currently telecommuting, which has impacted certain of our operations and may continue to do so over the long term. We may experience further limitations on employee resources in the future, including because of sickness of employees or their families. The effects of government actions and our own policies and those of third parties to reduce the spread of COVID-19 continues to negatively impact productivity and slow down or delay our ongoing and future clinical trials, preclinical studies and research and development activities, and may cause disruptions to our supply chain and impair our ability to execute our business development strategy. In the event that government authorities were to enhance current restrictions, our employees who currently are not telecommuting may no longer be able to access our facilities, and our operations may be further limited or curtailed.

As COVID-19 continues to spread and new variants emerge, we expect to experience ongoing disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays or difficulties in enrolling and maintaining patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials, including interruption in global shipping that may affect the transport of clinical trial materials;
- changes in local regulations as part of a response to the COVID-19 outbreak which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- 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 monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- risk that participants enrolled in our clinical trials will acquire COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events; and
- refusal of the FDA to accept data from clinical trials.

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

Our clinical trials have been, and we expect will continue to be, affected by the COVID-19 pandemic. For example, some of our clinical trial sites have slowed down or stopped further enrollment of new patients in clinical trials, denied access to site monitors and otherwise curtailed certain operations. Similarly, our ability to recruit and retain principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, may be adversely impacted. Our ongoing or planned clinical trials may also be impacted by interruptions or delays in the operations of the FDA and comparable foreign regulatory agencies. We and our CROs have also made certain adjustments to the operation of our trials in an effort to ensure the monitoring and safety of patients and minimize risks to trial integrity during the pandemic in accordance with the guidance issued by the FDA, and may need to make further adjustments in the future. Many of these adjustments are new and untested, may not be effective, and may have unforeseen effects on the enrollment, progress and completion of these trials and the findings from these trials. These events could delay our clinical trials, increase the cost of completing our clinical trials and negatively impact the integrity, reliability or robustness of the data from our clinical trials.

In addition, quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 or other infectious diseases could impact personnel at third-party manufacturing facilities upon which we rely, or the availability or cost of materials, which could disrupt the supply chain for our product candidates. To the extent our suppliers and service providers are unable to comply with their obligations under our agreements with them or they are otherwise unable to deliver or are delayed in delivering goods and services to us due to the COVID-19 pandemic, our ability to continue meeting clinical supply demand for our product candidates or otherwise advancing development of our product candidates may become impaired.

Furthermore, quarantines, shelter-in-place and similar government orders related to COVID-19 or other infectious diseases could cause a pause in manufacturing in both our external CMO’s and our pilot manufacturing facility, which could significantly delay the supply of clinical material. We have experienced some cancelled or delayed manufacturing operations at our CMO’s due to staffing issues related to COVID-19. In addition, even though our pilot manufacturing facility is fully operational, government orders or staffing issues related to COVID-19 illness could prevent us from operating the facility as intended. These events could delay our ability to manufacture clinical-scale materials for certain of our product candidates and otherwise delay the development of certain of our product candidates.

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

COVID-19 and actions taken to reduce its spread continue to rapidly evolve. The extent to which COVID-19 may impede the development of our product candidates, reduce the productivity of our employees, disrupt our supply chains, delay our clinical trials, reduce our access to capital or limit our business development activities, will depend on future developments, which are highly uncertain and cannot be predicted with confidence. To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this "Risk Factors" section, such as those relating to the timing and results of our clinical trials and our financing needs.

We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability and costs. If the use of our product candidates harms patients or is perceived to harm patients even when such harm is unrelated to our product candidates, our regulatory approvals could be revoked or otherwise negatively impacted and we could be subject to costly and damaging product liability claims.

The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. There is a risk that our product candidates may induce adverse events. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation;
- withdrawal of clinical trial participants;
- costs due to related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize our product candidates; and
- decreased demand for our product candidates, if approved for commercial sale.

We carry product liability insurance of $5.0 million per occurrence and $5.0 million aggregate limit. We believe our product liability insurance coverage is sufficient in light of our current clinical programs; however, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on drugs or medical treatments that had unanticipated adverse effects. A successful product liability claims, or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

Patients with cancer and other diseases targeted by our product candidates are often already in severe and advanced stages of disease and have both known and unknown significant pre-existing and potentially life-threatening health risks. During the course of treatment, patients may suffer adverse events, including death, for reasons that may be related to our product candidates, such as the patient death that occurred in our Phase 1 P-PSMA-101 trial. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact or end our opportunity to receive or maintain regulatory approval to market our products, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which we do not believe that an adverse event is related to our products, the investigation into the circumstance may be time-consuming or inconclusive. These investigations may interrupt our sales efforts, delay our regulatory approval process in other countries, or impact and limit the type of regulatory approvals our product candidates receive or maintain. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations.

We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel. The loss of the services of any of our executive officers, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements could result in delays in product development and harm our business.

We conduct substantially all of our operations at our facilities in San Diego. This region is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock options and RSUs that vest over time. The value to employees of stock options and RSUs that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. For example, in 2022, two of our executive officers provided notice of their resignation and retirement. Although we have employment agreements with certain of our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. Other than for Dr. Ostertag, our Executive Chairman, we do not maintain “key person” insurance policies on the lives of any of our executive officers. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel. We have experienced higher than normal turnover in the past year, due to the increasingly competitive hiring market in the biotechnology industry and if we cannot retain our existing employees and hire new employees to combat the impact of attrition, our operations may be adversely affected.

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

As of June 30, 2022, we had 290 employees. As we advance our research and development programs, we may be required to further increase the number of our employees and the scope of our operations, particularly in the areas of clinical development, manufacturing, quality, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage any future growth, we must:

- identify, recruit integrate, maintain and motivate additional qualified personnel;
- manage our development efforts effectively, including the initiation and conduct of clinical trials for our product candidates, both as monotherapy and in combination with other intra-portfolio product candidates; and
- improve our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to develop, manufacture and commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert financial and other resources, and a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time, to managing these growth activities.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

We face substantial competition, which may result in others discovering, developing or commercializing products more quickly or marketing them more successfully than us.

The development and commercialization of new products is highly competitive. We compete in the segments of the pharmaceutical, biotechnology and other related markets that develop immunotherapies for the treatment of cancer and gene therapies for inherited genetic disorders. 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 that we may develop or that would render any products that we may develop obsolete or non-competitive. Our competitors also may obtain marketing approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Moreover, with the proliferation of new drugs and therapies into oncology and genetic disorders, we expect to face increasingly intense

competition as new technologies become available. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. The highly competitive nature of and rapid technological changes in the biotechnology and pharmaceutical industries could render our product candidates or our technology obsolete, less competitive or uneconomical.

Other products in the same class as some of our product candidates have already been approved or are further along in development. As more product candidates within a particular class of biopharmaceutical products proceed through clinical development to regulatory review and approval, the amount and type of clinical data that may be required by regulatory authorities may increase or change. Consequently, the results of our clinical trials for product candidates in this class will likely need to show a risk benefit profile that is competitive with or more favorable than those products and product candidates in order to obtain marketing approval or, if approved, a product label that is favorable for commercialization. If the risk benefit profile is not competitive with those products or product candidates, we may have developed a product that is not commercially viable, that we are not able to sell profitably or that is unable to achieve favorable pricing or reimbursement. In such circumstances, our future product revenue and financial condition would be materially and adversely affected.

Specifically, there are many companies pursuing a variety of approaches to CAR-T therapies, including Adaptimmune Therapeutics plc, Allogene, Inc., Arcellx, Inc., Astellas Pharma, Inc., Autolus Ltd., Bluebird Bio, Inc., Cellectis S.A., Janssen Pharmaceuticals Inc., Juno Therapeutics, Inc. (acquired by Celgene Corporation, now a Bristol-Meyers Squibb company), Gracell Biotechnologies Inc., Kite Pharma, Inc. (a Gilead Sciences, Inc. company), Legend Biotech Corporation, Novartis AG and Takeda. Immunotherapy and gene therapy approaches are further being pursued by many smaller biotechnology companies as well as larger pharmaceutical companies. We also face competition from non-cell-based or other gene therapy treatments offered by companies such as Amgen Inc., AstraZeneca plc, Beam Therapeutics, Inc, Bristol-Myers Squibb Company, F. Hoffman-La Roche AG, Generation Bio, Inc., GlaxoSmithKline plc, Merck & Co., Inc. PassageBio, Inc. and Pfizer Inc. Many of our competitors, either alone or with their collaboration partners, have substantially greater financial, technical and other resources, such as larger research and development staff and/or greater expertise in research and development, manufacturing, preclinical testing and conducting clinical trials.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and subject enrollment for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

The key competitive factors affecting the success of all of our programs are likely to be their efficacy, safety, convenience, and availability of reimbursement. If we are not successful in developing, commercializing and achieving higher levels of reimbursement than our competitors, we will not be able to compete against them and our business would be materially harmed.

We or the third parties upon whom we depend may be adversely affected by earthquakes, fires or other natural disasters.

Our headquarters, main research facility and pilot manufacturing facility are located in San Diego, California, which in the past has experienced severe earthquakes and fires. If these earthquakes, fires, other natural disasters, terrorism and similar unforeseen events beyond our control prevented us from using all or a significant portion of our headquarters or research facility, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. We do not have a disaster recovery or business continuity plan in place and may incur substantial expenses as a result of the absence or limited nature of our internal or third-party service providers' disaster recovery and business continuity plans, which could have a material adverse effect on our business. Furthermore, integral parties in our supply chain are operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our ability to conduct our clinical trials, our development plans, business, financial condition or results of operations.

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

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. Unused U.S. federal net operating losses, or NOLs, for taxable years beginning before January 1, 2018, may be carried forward to offset future taxable income, if any, until such unused NOLs expire. Under current law, U.S. federal NOLs incurred in taxable years beginning after December 31, 2017, can be carried forward indefinitely, but the deductibility of such U.S. federal NOLs in taxable 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 federal tax laws.

As of December 31, 2021, we had $23.3 million of U.S. federal NOLs that will begin to expire in 2032, and $329.9 million of U.S. federal NOLs that can be carried forward indefinitely under current law. As of December 31, 2021, we also had aggregate U.S. federal orphan drug credits and research and development, or R&D, credits of approximately $33.2 million. Our NOL carryforwards and R&D credits are subject to review and possible adjustment by the U.S. and state tax authorities.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50 percentage point change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOL carryforwards, R&D credits and certain other tax attributes to offset its post-change income or taxes may be limited. This could limit the amount of NOLs, R&D credit carryforwards or other applicable tax attributes that we can utilize annually to offset future taxable income or tax liabilities. Subsequent ownership changes and changes to the U.S. tax rules in respect of the utilization of NOLs, R&D credits and other applicable tax attributes carried forward may further affect the limitation in future years. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, if we earn net taxable income, we may be unable to use all or a material portion of our net operating loss carryforwards and other tax attributes, which could potentially result in increased future tax liability to us and adversely affect our future cash flows.

**** Changes in healthcare law and implementing regulations, as well as changes in healthcare policy, may impact our business in ways that we cannot currently predict, and may have a significant adverse effect on our business and results of operations.***

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval. Among policy makers and payors in the United States and elsewhere, including in the EU, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

The Affordable Care Act substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The Affordable Care Act, among other things: (1) introduced a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics that are inhaled, infused, instilled, implanted or injected and not generally dispensed through retail community pharmacies; (2) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program; (3) established a branded prescription drug fee that pharmaceutical manufacturers of branded prescription drugs must pay to the federal government; (4) expanded the list of covered entities eligible to participate in the 340B drug pricing program by adding new entities to the program; (5) established 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; (6) extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; (7) expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability; (8) created a licensure framework for follow on biologic products; (9) established a Center for Medicare and Medicaid Innovation at CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending; and (10) created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research.

There have been executive, judicial and Congressional challenges to certain aspects of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, the legislation enacted in 2017 included a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the Affordable Care Act's mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amended the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the Affordable Care Act will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit

access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the Biden administration will impact the Affordable Care Act and our business or financial condition.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and, due to legislative amendments to the statute, the Infrastructure Investment and Jobs Act, the BBA and the Coronavirus Aid, Relief, and Economic Security Act, will remain in effect through 2030 unless additional Congressional action is taken. These reductions have been suspended from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester. In January 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. Additional changes that may affect our business include the expansion of new programs such as Medicare payment for performance initiatives for physicians, also referred to as the Quality Payment Program, under the Medicare Access and CHIP Reauthorization Act of 2015. In November 2019, CMS issued a final rule finalizing the changes to the Quality Payment Program. At this time, it is unclear how the introduction of the Quality Payment Program will impact overall physician reimbursement under the Medicare Program. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. In addition, new laws may result in additional reductions in Medicare and other healthcare funding, which may materially adversely affect customer demand and affordability for our products and, accordingly, the results of our financial operations.

Also, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which have resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, President Trump announced several executive orders related to prescription drug pricing that attempt to implement several of the Trump administration's proposals. As a result, the FDA released a final rule and guidance in September 2020 implementing a portion of the importation executive order providing pathways for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the Department of Health and Human Services, or HHS, finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. The implementation of the rule has been delayed until January 1, 2027. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries. As a result of litigation challenging the Most Favored Nation model, on December 27, 2021, CMS published a final rule that rescinded the Most Favored Nation model interim final rule. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. No legislation or administrative actions have been finalized to implement these principles. In addition, Congress is considering drug pricing as part of other reform initiatives.

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

We expect that these and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and lower reimbursement and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of cost-containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs once marketing approval is obtained.

Further, it is possible that additional governmental action will be taken in response to the COVID-19 pandemic.

In the European Union, coverage and reimbursement status of any product candidates for which we obtain regulatory approval are provided for by the national laws of EU Member States. The requirements may differ across the EU Member States. Also, at national level, actions have been taken to enact transparency laws regarding payments between pharmaceutical companies and health care professionals.

We are subject to applicable fraud and abuse, transparency, government price reporting, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Healthcare providers and third-party payors will play a primary role in the recommendation and prescription of any future product candidates we may develop and any product candidates for which we obtain marketing approval. Our current and future arrangements with clinical investigators, third-party payors, healthcare provider and customers expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may affect the business or financial arrangements and relationships through which we research, market, sell and distribute our products. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits any person or entity from, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of an item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term "remuneration" has been broadly interpreted to include anything of value. The federal Anti-Kickback Statute has also been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, and purchasers, on the other the other hand. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but these exceptions and safe harbors are narrowly drawn. Practices that are alleged to be intended to induce prescribing, purchases or recommendations, or include any payments of more than fair market value, may be subject to scrutiny if they do not qualify for an exception or safe harbor;
- federal civil and criminal false claims laws, such as the civil False Claims Act, or FCA, which can be enforced by private citizens through civil qui tam actions, and the Civil Monetary Penalties Law prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented, false, fictitious or fraudulent claims for payment of federal funds, and knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. For example, pharmaceutical companies have been prosecuted under the FCA in connection with, among other things their alleged off-label promotion of drugs, engaging in improper consulting arrangements with physicians, concealing price concessions in the pricing information submitted to the government for government price reporting purposes, and providing free product to customers with the expectation that the customers would bill federal health care programs for the product. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. In addition, manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims;
- The Health Insurance Portability and Accountability Act of 1996, or HIPAA, which, among other things, imposes criminal liability for executing or attempting to execute a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and creates federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their implementing regulations, which imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon covered entities, including certain healthcare providers, health plans, and healthcare clearinghouses, as well as their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, and their subcontractors that use, disclose or otherwise process individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- the federal transparency requirements under the Physician Payments Sunshine Act, created under the Affordable Care Act, which requires, among other things, certain manufacturers of drugs, devices, biologics and medical supplies reimbursed

under Medicare, Medicaid, or the Children's Health Insurance Program to report to CMS information related to payments and other transfers of value provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other health care professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members;

- analogous state, local and foreign laws and regulations, such as anti-kickback and false claims laws, that may impose similar or more prohibitive restrictions, and may apply to items or services reimbursed by any non-governmental third-party payors, including private insurers; and
- state and foreign laws that require pharmaceutical companies to implement compliance programs, comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or to track and report gifts, compensation and other remuneration provided to physicians and other health care providers, state and local laws that require the registration of pharmaceutical sales representatives, and other federal, state and foreign laws that govern the privacy and security of health information or personally identifiable information in certain circumstances, including state health information privacy and data breach notification laws which govern the collection, use, disclosure, and protection of health-related and other personal information, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus requiring additional compliance efforts.

We may also be subject to federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers. We have entered into consulting and scientific advisory board arrangements with physicians and other healthcare providers, some of which include provisions of stock options, including some who could influence the use of our product candidates, if approved. Because of the complex and far-reaching nature of these laws, regulatory agencies may view these transactions as prohibited arrangements that must be restructured, or discontinued, or for which we could be subject to other significant penalties. We could be adversely affected if regulatory agencies interpret our financial relationships with providers who may influence the ordering of and use our product candidates, if approved, to be in violation of applicable laws.

Federal and state enforcement bodies have continued their scrutiny of interactions between healthcare companies and healthcare providers, which has led to significant investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time- and resource-consuming and can divert management's attention from the business. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. If our operations are found to be in violation of any of these laws or any other current or future governmental laws and regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could substantially disrupt our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Risks Related to Our Intellectual Property

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

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our platform technologies and product candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel discoveries and technologies that are important to our business. Our pending and future patent applications may not result in patents being issued which protect our product candidates or their intended uses or which effectively prevent others from commercializing competitive technologies, products or product candidates.

Obtaining and enforcing patents is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications or maintain and/or enforce patents that may issue based on our patent applications, at a reasonable cost or in a timely manner, including as a result of the COVID-19 pandemic impacting our or our licensors' operations. It is also possible that

we will fail to identify patentable aspects of our research and development results before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

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

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

Further, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates or their intended uses, and as a result the impact of such third-party intellectual property rights upon the patentability of our own patents and patent applications, as well as the impact of such third-party intellectual property upon our freedom to operate, is highly uncertain. Patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our patents or pending patent applications may be challenged in the courts or patent offices in the United States and abroad. For example, we may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in post-grant review procedures, oppositions, derivations, reexaminations, or *inter partes* review proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Any failure to obtain or maintain patent protection with respect to our product candidates could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction.

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

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. If we fail to comply with our obligations under these agreements, including due to the impact of the COVID-19 pandemic on our business operations, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license.

We may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend considerable time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current product candidates or future products, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

In many cases, patent prosecution of our licensed technology is controlled solely by the licensor. If our licensors fail to obtain and maintain patent or other protection for the proprietary intellectual property we license from them, including due to the impact of the COVID-19 pandemic on our licensors' business operations, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business and our competitors could market competing products using the intellectual property. In certain 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. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing 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 partners; and
- the priority of invention of patented technology.

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

In the future, we may need to obtain additional licenses of third-party technology that may not be available to us or are available only on commercially unreasonable terms, and which may cause us to operate our business in a more costly or otherwise adverse manner that was not anticipated.

We currently have rights to intellectual property covering our product candidates and other proprietary technologies. Other pharmaceutical companies and academic institutions may also have filed or are planning to file patent applications potentially relevant to our business. From time to time, in order to avoid infringing these third-party patents, we may be required to license technology from additional third parties to further develop or commercialize our product candidates. Should we be required to obtain licenses to any third-party technology, including any such patents required to manufacture, use or sell our product candidates, such licenses may not be available to us on commercially reasonable terms, or at all. The inability to obtain any third-party license required to develop or commercialize any of our product candidates could cause us to abandon any related efforts, which could seriously harm our business and operations.

The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical

development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us.

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

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

We have pending U.S. and foreign patent applications in our portfolio; however, we cannot predict:

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

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

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

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

- others may be able to make product candidates that are similar to ours but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;

- issued patents that we own or have exclusively licensed may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- we cannot predict the scope of protection of any patent issuing based on our patent applications, including whether the patent applications that we own or in-license will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries;
- the claims of any patent issuing based on our patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties;
- if enforced, a court may not hold that our patents are valid, enforceable and infringed;
- we may need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property;
- we may fail to adequately protect and police our trademarks and trade secrets; and
- the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patents and patent applications.

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

If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates.

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our product candidates without infringing the intellectual property and other proprietary rights of third parties. Third parties may allege that we have infringed or misappropriated their intellectual property. For example, in early 2019, we received a letter from a third party alleging that we have used materials received from the third party in an unauthorized manner and stating a belief that we will infringe certain patents relating to the use of a safety switch in our CAR-T products. While we have denied that we used any of the third party's materials in an unauthorized manner and believe that the patents will not be infringed, are invalid, or both, we cannot predict whether the third party will persist in its allegations or whether litigation will ensue. Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming and, even if resolved in our favor, is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our product candidates. We cannot assure you that our product candidates and other proprietary technologies we may develop will not infringe existing or future patents owned by third parties. Third parties may assert infringement claims against us based on existing or future intellectual property rights. We may not be aware of patents that have already been issued and that a third party, for example, a competitor in the fields in which we are developing our product candidates, might assert are infringed by our current or future product candidates, including claims to compositions, formulations, methods of manufacture or methods of use or treatment that cover our product candidates. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our product candidates and other proprietary technologies we may develop, could be found to be infringed by our product candidate. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. Our competitors in both the United States and abroad,

many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our product candidates. The pharmaceutical and biotechnology industries have produced a considerable number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity may be difficult. For example, in the United States, proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents, and there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on our business and operations. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

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

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

Competitors or other third parties may infringe our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or insufficient written description. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention, or decide that the other party's use of our patented technology falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1). An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other

interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Moreover, we cannot assure you that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

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

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

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

We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of former employers or competitors. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may become subject to claims that we caused an employee to breach the terms of their non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor.

While we may litigate to defend ourselves against these claims, even if we are successful, litigation could result in substantial costs and could be a distraction to management. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to our product candidates, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

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

Patents are of national or regional effect, and filing, prosecuting and defending patents on all of our product candidates throughout the world would be prohibitively expensive. As such, our intellectual property rights in some countries outside the United States can be less extensive than those in the United States and we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products or technology and may export otherwise infringing products or technology to territories where we have patent protection, but enforcement rights are not as strong as those in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Further, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals or biologics, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. 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, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any such lawsuits that we initiate and the damages and other remedies awarded, if any, may not be commercially meaningful. Similarly, if our trade secrets are disclosed in a foreign jurisdiction, competitors worldwide could have access to our proprietary information and we may be without satisfactory recourse. Such disclosure could have a material adverse effect on our business. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. In

addition, certain developing countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third-party, which could materially diminish the value of those patents. In addition, many countries limit the enforceability of patents against government agencies or government contractors. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs, and may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our owned and licensed patents. Recent patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act, or the Leahy-Smith Act, signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. After March 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third-party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before we file an application covering the same invention, could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (1) file any patent application related to our product candidates and other proprietary technologies we may develop or (2) invent any of the inventions claimed in our or our licensor's patents or patent applications. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing the claimed invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, in the 2013 case *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, the U.S. Supreme Court held that certain claims to DNA molecules are not patentable. While we do not believe that any of the patents owned or licensed by us will be found invalid based on this decision, we cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents.

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

Periodic maintenance fees, renewal fees, annuities fees and various other governmental fees on patents and/or patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent and/or patent application. The USPTO and various foreign governmental patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse, including due to the effect of the COVID-19 pandemic on us or our patent maintenance vendors, can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not

limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our product candidates, our competitive position would be adversely affected.

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

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

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

We may become subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Our licensors may have relied on third-party consultants or collaborators or on funds from third parties, such as the U.S. government, such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights or other rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

Patent rights are of limited duration. In the United States, if all maintenance fees are paid timely, the natural expiration of a patent is generally 20 years after its first effective filing date. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such product candidates are commercialized. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from biosimilar or generic products. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours. Upon issuance in the United States, a patent's life can be increased based on certain delays caused by the USPTO, but this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. A patent term extension based on regulatory delay may be available in the United States. However, only a single patent can be extended for each marketing approval, and any patent can be extended only once, for a single product. Moreover, the scope of protection during the period of the patent term extension does not extend to the full scope of the claim, but instead only to the scope of the product as approved. Laws governing analogous patent term extensions in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family. Additionally, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration and may take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to launch their product earlier than might otherwise be the case, and our revenue could be reduced, possibly materially.

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

Our current or future trademarks or trade names may be challenged, infringed, circumvented or declared generic or descriptive, or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

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

trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Risks Related to Our Common Stock

**** The market price of our common stock has been and may continue to be volatile or may decline regardless of our operating performance and you could lose all or part of your investment.***

The market price of our common stock may fluctuate significantly in response to numerous factors, many of which are beyond our control, including:

- overall performance of the equity markets;
- our operating performance and the performance of other similar companies;
- the published opinions and third-party valuations by banking and market analysts;
- results from our ongoing clinical trials and future clinical trials with our current and future product candidates or of our competitors;
- changes in our projected operating results that we provide to the public, our failure to meet these projections or changes in recommendations by securities analysts that elect to follow our common stock;
- regulatory or legal developments in the United States and other countries;
- changes in the structure of healthcare payment systems;
- the level of expenses related to future product candidates or clinical development programs;
- our failure to achieve product development goals in the timeframe we announce;
- announcements of acquisitions, strategic alliances or significant agreements by us or by our competitors;
- recruitment or departure of key personnel;
- the economy as a whole and market conditions in our industry;
- the expiration of market standoff or contractual lock-up agreements;
- the size of our market float;
- the ongoing and future impact of the COVID-19 pandemic and actions taken to slow its spread; and
- any other factors discussed in this Quarterly Report on Form 10-Q.

In addition, the stock markets in general, and the Nasdaq Global Market in particular, have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many immuno-oncology and gene therapy companies. Stock prices of many of these companies have fluctuated in a manner unrelated or disproportionate to their operating performance, and we have in the past experienced volatility that has been unrelated or disproportionate to our operating performance. From January 1, 2021 through August 8, 2022, the closing price of our common stock has ranged between $1.87 and $11.91 per share. The trading prices for common stock of other biopharmaceutical companies have also been highly volatile as a result of the COVID-19 pandemic and anticipated increase in interest rates. In the past, stockholders have filed securities class action litigation following periods of market volatility. If we were to become involved in securities litigation, it could subject us to substantial costs, divert resources and the attention of management from our business and adversely affect our business.

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

As of August 8, 2022, our executive officers, directors, five percent stockholders and their affiliates beneficially owned approximately 55% of our voting stock. Therefore, these stockholders have the ability to influence us through their ownership positions. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders, acting together, may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

In addition, Dr. Ostertag, our Executive Chairman, a member of our board of directors and the beneficial owner of approximately 12% of our voting stock as of August 8, 2022, is the sole director of Demeetra AgBio, Inc., or Demeetra, serves as its President and Secretary and together with his affiliated entities, owns on a fully-diluted basis, 63% of its capital stock. Further, Dr. Ostertag is also a member of the board of directors of Hera Testing Laboratories, Inc., or Hera, and served as its Chief Executive Officer from inception until July 2015 and, together with his affiliated entities, owns on a fully-diluted basis, 42% of its capital stock.

As a result, the interests of Dr. Ostertag may not be aligned with the interests of you and our other stockholders with respect to our relationships with Hera and Demeetra, and he may from time to time be incentivized to take certain actions that benefit his interests in those other entities and that you and our other stockholders do not view as being in your interest as investors in our company.

If we fail to maintain an effective system of internal controls in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of the Nasdaq Stock Market. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal controls over financial reporting.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected on a timely basis. We may discover material weaknesses in our system of internal financial and accounting controls and procedures in the future that could result in a material misstatement of our consolidated financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls over financial reporting, we may not be able to produce timely and accurate financial statements. If that were to happen, our investors could lose confidence in our reported financial information, the market price of our stock could decline, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities.

General Risk Factors

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

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. In addition, we are subject to the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC, and various requirements the Nasdaq Global Select Market have imposed on public companies. In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Recent legislation permits smaller "emerging growth companies" to implement many of these requirements over a longer period and up to five years from the completion of our initial public offering. We intend to continue to take advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costlier. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain our current levels of such coverage. We estimate that we annually incur approximately $4.0 million to $5.0 million in additional expenses to comply with the requirements imposed on us as a public company.

Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with the regulations of the FDA and non-U.S. regulators, provide accurate information to the FDA and non-U.S. regulators, 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, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations.

If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; a material disruption of our product candidates' development programs; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences.

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit confidential information (including but not limited to intellectual property, proprietary business information and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have outsourced elements of our operations to third parties, and as a result we manage a number of third-party contractors who have access to our confidential information. Our ability to monitor these third parties' cybersecurity practices is limited, and these third parties may not have adequate information security measures in place.

Cyberattacks, malicious internet-based activity, and online and offline fraud are prevalent and continue to increase. These threats are becoming increasingly difficult to detect. These threats come from a variety of sources. In addition to traditional computer "hackers," threat actors, personnel (such as through theft or misuse), sophisticated nation-states, and nation-state-supported actors now engage in attacks.

We and the third parties upon which we rely may be subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats. Ransomware attacks, including those perpetrated by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Similarly, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems or the third-party information technology systems that support us and our services.

Any of the previously identified or similar threats could cause a security incident or other interruption. A security incident or other interruption could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to data or could disrupt our ability (and that of third parties upon whom we rely) to provide our services. If such an event were to occur, it could result in a material disruption of our product development programs and our business operations. These threats pose a risk to the security of our systems, the confidentiality and the availability and integrity of our data, and these risks apply both to us, and to third parties on whose systems we rely for the conduct of our business.

We may expend significant resources or modify our business activities (including our clinical trial activities) in an effort to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures, industry-standard or reasonable security measures to protect our information technology systems and data. Despite the implementation of security measures, given their size and complexity and the increasing amounts of confidential information that we and the third parties upon who we rely maintain, there can be no assurance that these measures will be effective. We may be unable to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred. Despite our efforts to identify and remediate vulnerabilities, if any, in our information technology systems, our efforts may not be successful. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

While we have not experienced any such system failure, accident or security breach to date, we cannot be certain that our data protection efforts and our investment in information technology will prevent a security incident from occurring. If we suffer such an incident, applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary expenditures; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may cause delays in the development of our product candidates, cause customers to stop using our products or services, deter new customers from using our products or services, and negatively impact our ability to grow and operate our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient of protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims. Our risks are likely to increase as we continue to expand our business, grow our customer base, and process, store, and transmit increasingly large amounts of proprietary and sensitive data.

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the Biden administration and Congress have proposed various U.S. federal tax law changes, which if enacted could have a material impact on our business, cash flows, financial condition or results of operations. In addition, it is uncertain if and to what extent various states will conform to federal tax laws. Future tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

**** Failure to comply with health and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business.***

We process personal data and other sensitive data (including health data we collect about trial participants in connection with clinical trials); proprietary and confidential business data; trade secrets; intellectual property; and sensitive third-party data. Our data processing activities subject us to numerous data privacy and security obligations. Accordingly, we and any potential collaborators may be subject to numerous federal, state, and foreign data privacy and protection obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts, and other obligations that govern the processing of personal data by us and on our behalf.

Data privacy and information security have become significant issues in the United States, countries in Europe, and in other countries in which we operate. The legal and regulatory framework for privacy and security issues is rapidly evolving, and is expected to increase our compliance costs and exposure to liability. In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. For example, The California Consumer Privacy Act of 2018, or CCPA, imposes obligations on businesses to which it

applies. These obligations include, but are not limited to, providing specific disclosures in privacy notices and affording California residents certain rights related to their personal data. The CCPA allows for statutory fines for noncompliance (up to $7,500 per violation). Further, it is anticipated that the California Privacy Rights Act of 2020, or CPRA, effective January 1, 2023, will expand the CCPA. For example, the CPRA establishes a new California Privacy Protection Agency to implement and enforce the CCPA (as amended), which could increase the risk of an enforcement action. Other states have enacted data privacy laws. For example, other states, including Colorado, Connecticut, Utah and Virginia, have passed privacy laws which differ from the CPRA and all of which become effective in 2023. In addition, data privacy and security laws have been proposed at the federal, state, and local levels in recent years, which could further complicate compliance efforts. If we are or become subject to these laws and/or new or amended data privacy laws, the risk of enforcement actions against us could increase because we may be subject to obligations under applicable regulatory frameworks and the number of individuals or entities that could initiate actions against us may increase (including individuals via a private right of action), in addition to further complicating our compliance efforts. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA, as amended by HITECH, which imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. If we violate HIPAA, we may be subject to significant penalties. Further, privacy advocates and industry groups have proposed, and may propose in the future, standards with which we are legally or contractually bound to comply.

Internationally, virtually every jurisdiction in which we operate has established its own data security and privacy legal framework that may also apply to health-related and other personal information obtained outside of the United States, including but not limited to the European Union's General Data Protection Regulation ("EU GDPR"), the United Kingdom's GDPR ("UK GDPR"), which impose strict requirements for processing the personal data of individuals. For example, under the EU GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines of up to 20 million euros or 4% of annual global revenue, whichever is greater. Further, individuals may initiate litigation related to our processing of their personal data. The unstable nature of European Union's data protection landscape may result in possible significant operational costs for internal compliance and risk to our business.

Certain jurisdictions have enacted data localization laws and cross-border personal data transfer laws. For example, absent appropriate safeguards or other circumstances, the EU GDPR generally restricts the transfer of personal data to countries such as the United States that do not provide an adequate level of personal data protection. The European Commission released a set of "Standard Contractual Clauses" that are designed to be a valid mechanism by which entities can transfer personal data out of the European Economic Area (EEA) to jurisdictions that the European Commission has not found to provide an adequate level of protection. Currently, these Standard Contractual Clauses are a valid mechanism to transfer personal data outside of the EEA. The Standard Contractual Clauses, however, require parties that rely upon that legal mechanism to comply with additional obligations, such as conducting transfer impact assessments to determine whether additional security measures are necessary to protect the at-issue personal data. Moreover, due to potential legal challenges, there exists some uncertainty regarding whether the Standard Contractual Clauses will remain a valid mechanism for transfers of personal data out of the EEA. In addition, laws in Switzerland and the UK similarly restrict transfers of personal data outside of those jurisdictions to countries such as the United States that do not provide an adequate level of personal data protection. Any of these or other similar restrictions and obligations could increase the cost and complexity of doing business in foreign jurisdictions. If we cannot implement valid compliance mechanisms for cross-border personal data transfers, we may face increased exposure to regulatory actions, substantial fines, and injunctions against processing or transferring personal data from Europe or elsewhere. The inability to import personal data to the United States could significantly and negatively impact our business operations, including by limiting our ability to conduct clinical trial activities in Europe, the United Kingdom and elsewhere; limiting our ability to collaborate with third parties, such as contract research organizations as well as other service providers, that are subject to European and other data privacy and security laws; or requiring us to increase our personal data processing capabilities and infrastructure in Europe and/or elsewhere at significant expense.

Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations which could impact our compliance posture. For example, any failure by a third-party processor to comply with applicable law, regulations, or contractual obligations could result in adverse effects, including inability to operate our business and proceedings against us by governmental entities or others. Failure to comply, or any perceived failure to comply, with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties investigations, fines, audits, and inspections), private litigation (including class-related claims), breach reporting requirements, additional reporting requirements and/or oversight, bans on processing personal data, orders to destroy or not use personal data, and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business. Any of these events could have a material adverse effect on

our reputation, business, or financial condition, including but not limited to: loss of customers, interruptions or stoppages in our business operations (including, as relevant, clinical trials), inability to process personal data or to operate in certain jurisdictions, expenditure of time and resources to defend any claim or inquiry, or revision or restructuring of our operations.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations.

U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, or collectively, Trade Laws, prohibit, among other things, companies and their employees, agents, CROs, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We also expect our non-U.S. activities to increase over time. We expect to rely on third parties for research, preclinical studies, and clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other marketing approvals. We can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We, and the third parties with whom we share our facilities, are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Each of our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Each of our operations also produce hazardous waste products. 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. We could be held liable for any resulting damages in the event of contamination or injury resulting from the use of hazardous materials by us or the third parties with whom we share our facilities, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

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 maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research and development. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

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

As a result of the COVID-19 pandemic and actions taken to slow its spread, the global credit and financial markets have recently experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy has been and may continue to be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, 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 and other partners may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

Additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner, we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

Pursuant to our 2020 Equity Incentive Plan, or the 2020 Plan, our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. The number of shares of our common stock reserved for issuance under our 2020 Plan will automatically increase on January 1 of each calendar year, starting on January 1, 2021 through January 1, 2030, in an amount equal to the lesser of (i) 5% of the total number of shares of our common stock outstanding on the last day of the calendar month before the date of each automatic increase, or (ii) a lesser number of shares determined by our board of directors prior to the applicable January 1st. If our board of directors elects to increase the number of shares available for future grant by the maximum amount each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

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 for us because pharmaceutical companies have experienced significant stock price volatility in recent years. 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.

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

The trading market for our common stock could be influenced by the research and reports that industry or securities analysts publish about us or our business. 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 the clinical trials and operating results fail to meet the expectations of analysts, the trading price for our common stock would be negatively affected. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our common stock price and trading volume to decline.

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

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

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

Future changes in financial accounting standards or practices may cause adverse and unexpected revenue fluctuations and adversely affect our reported results of operations.

Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our reported financial position or results of operations. Financial accounting standards in the United States are constantly under review and new pronouncements and varying interpretations of pronouncements have occurred with frequency in the past and are expected to occur again in the future. As a result, we may be required to make changes in our accounting policies. Those changes could affect our financial condition and results of operations or the way in which such financial condition and results of operations are reported. We intend to invest resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from business activities to compliance activities.

We are an "emerging growth company," and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an "emerging growth company" as defined in the JOBS Act, and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- 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 regarding executive compensation; and
- not being required to hold a non-binding advisory vote on executive compensation or obtain stockholder approval of any golden parachute payments not previously approved.

In addition, as an "emerging growth company" the JOBS Act allows us to delay adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements are made applicable to private companies, unless we later irrevocably elect not to avail ourselves of this exemption. We have elected to use this extended transition period under the JOBS Act. As a result, our consolidated financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies, which may make comparison of our financials to those of other public companies more difficult.

We cannot predict if investors will find our common stock less attractive because we will 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 more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering, (b) in which we have total annual gross revenue of at least $1.07 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30 and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock.

Our status as a Delaware corporation and the anti-takeover provisions of the Delaware General Corporation Law may discourage, delay or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change of control would be beneficial to our existing stockholders. In addition, our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that may make the acquisition of our company more difficult, including the following:

- a classified board of directors with three-year staggered terms, which could delay the ability of stockholders to change the membership of a majority of our board of directors;
- the ability of our board of directors to issue shares of preferred stock and to determine the price and other 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 exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of our board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board 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 a majority vote of our entire board of directors, the chairman of our board of directors or our Chief Executive Officer, which could delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors;

- the requirement for the affirmative vote of holders of at least 66-2/3% of the voting power of all of the then-outstanding shares of the voting stock, voting together as a single class, to amend the provisions of our amended and restated certificate of incorporation relating to the management of our business or our amended and restated bylaws, which may inhibit the ability of an acquirer to affect such amendments to facilitate an unsolicited takeover attempt; and
- advance notice procedures with which stockholders must comply 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.

In addition, as a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation Law. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a certain period of time. A Delaware corporation may opt out of this provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of this provision.

These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including delay or impede a merger, tender offer or proxy contest involving our company. The existence of these provisions could negatively affect the price of our common stock and limit opportunities for you to realize value in a corporate transaction.

Our amended and restated certificate of incorporation designates the state courts in the State of Delaware or, if no state court located within the State of Delaware has jurisdiction, the federal court for the District of Delaware, as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could discourage lawsuits against our company and our directors, officers and employees.

Our amended and restated certificate of incorporation provides that, to the fullest extent permitted by law, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware) will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (1) any derivative action or proceeding brought on our behalf; (2) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders; (3) any action or proceeding asserting a claim against us or any of our current or former directors, officers or other employees, arising out of or pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws; (4) any action or proceeding to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws; (5) any action or proceeding as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware; and (6) any action asserting a claim against us or any of our directors, officers or other employees, governed by the internal affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

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 lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

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

Unregistered Sales of Equity Securities

None.

Use of Proceeds

We completed our initial public offering pursuant to a Registration Statement on Form S-1 (File No. 333-239321) that was declared effective on July 9, 2020.

Upon receipt, the net proceeds from our initial public offering were held in cash and cash equivalents, primarily bank money market accounts. Through June 30, 2022, we have used approximately $140.0 million of the net proceeds from our initial public offering. We are investing the remaining funds in a combination of short- and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government. There has been no material change in the planned use of proceeds from our initial public offering from those disclosed in our 2021 Annual Report.

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
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-39376), filed with the SEC on July 14, 2020).
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-39376), filed with the SEC on July 14, 2020).
4.1	Form of Common Stock Certificate of the Registrant (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-239321), filed with the SEC on June 19, 2020).
4.2	Amended and Restated Investors' Rights Agreement, by and among the Registrant and certain of its stockholders, dated June 24, 2020 (incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-239321), filed with the SEC on July 6, 2020).
4.3	Form of Warrant issued to Oxford Finance LLC, dated July 25, 2017 (incorporated by reference to Exhibit 4.3 to the Registrant's Registration Statement on Form S-1 (File No. 333-239321), filed with the SEC on June 19, 2020).
4.4	Form of Warrant issued to Oxford Finance LLC, dated August 13, 2018 (incorporated by reference to Exhibit 4.4 to the Registrant's Registration Statement on Form S-1 (File No. 333-239321), filed with the SEC on June 19, 2020).
4.5	Form of Warrant issued to Oxford Finance LLC, dated February 11, 2019 (incorporated by reference to Exhibit 4.5 to the Registrant's Registration Statement on Form S-1 (File No. 333-239321), filed with the SEC on June 19, 2020).
10.1+	Poseida Therapeutics, Inc. Amended and Restated Non-Employee Director Compensation Policy.
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Exchange Act, 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 Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibit 101. INS)

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

\+ Indicates management contract or compensatory plan.

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.

POSEIDA THERAPEUTICS, INC.

Date: August 11, 2022

By: /s/ Mark J. Gergen
Mark J. Gergen, J.D.
Chief Executive Officer
(Principal Executive Officer)

Date: August 11, 2022

By: /s/ Johanna M. Mylet
Johanna M. Mylet, C.P.A.
Chief Financial Officer
(Principal Financial Officer)

POSEIDA THERAPEUTICS, INC.
NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

ADOPTED: JULY 1, 2020
EFFECTIVE: JULY 9, 2020
AMENDED AND RESTATED: JULY 23, 2021
AMENDED AND RESTATED: MAY 24, 2022 (THE "*AMENDMENT DATE*")

Each member of the Board of Directors (the "***Board***") of Poseida Therapeutics, Inc. (the "***Company***") who is a non-employee director of the Company (each such member, a "***Non-Employee Director***") will receive the compensation described in this Non-Employee Director Compensation Policy (the "***Director Compensation Policy***") for his or her Board service.

The Director Compensation Policy may be amended at any time in the sole discretion of the Board or the Compensation Committee of the Board (the "***Compensation Committee***").

A Non-Employee Director may decline all or any portion of his or her compensation by giving notice to the Company prior to the date cash is to be paid or equity awards are to be granted, as the case may be.

Annual Cash Compensation

Each Non-Employee Director will receive the cash compensation set forth below for service on the Board. The annual cash compensation amounts will be payable in equal quarterly installments, in arrears following the end of each quarter in which the service occurred, pro-rated for any partial months of service. All annual cash fees are vested upon payment.

1. Annual Board Service Retainer:
   a. All Eligible Directors: $40,000
   b. Independent Chairman of the Board (in addition to Eligible Director Annual Board Service Retainer): $30,000
   c. Lead Independent Director (in addition to Eligible Director Annual Board Service Retainer): $20,000

2. Annual Committee Member Service Retainer:
   a. Member of the Audit Committee: $7,500
   b. Member of the Compensation Committee: $5,000
   c. Member of the Nominating and Corporate Governance Committee: $4,000

3. Annual Committee Chair Service Retainer (in lieu of the Annual Committee Member Service Retainer):
   a. Chairman of the Audit Committee: $15,000
   b. Chairman of the Compensation Committee: $10,000
   c. Chairman of the Nominating and Corporate Governance Committee: $8,000

Equity Compensation

Equity awards will be granted under the Company's 2020 Equity Incentive Plan (the "***Plan***"). All equity awards granted under this Director Compensation Policy will be Nonstatutory Stock Options or RSUs (each as defined in the Plan). Nonstatutory Stock Options will have an exercise price per share equal to 100% of the Fair Market Value (as defined in the Plan) of the underlying common stock of the Company on the date of grant, and a term of ten years from the date of grant (subject to earlier termination in connection with a termination of service as provided in the Plan, provided that upon a termination of service other than for death, Disability or Cause (as each such term is defined in the Plan), the post-termination exercise period will be 12 months from the date of termination).

(a) Automatic Equity Grants.

(i) Initial Grant for New Directors. Without any further action by the Board, each person who, on or after the Amendment Date, is elected or appointed for the first time to be a Non-Employee Director (a "***New Director***") will automatically, upon the date of his or her initial election or appointment to be a Non-Employee Director (or, if such date is not a market trading day, the first market trading day thereafter) (such date, the "***Initial Award Grant Date***"), be granted a Nonstatutory Stock Option (an "***Initial Option Grant***") and RSUs (an "***Initial RSU Grant***," together with the Initial Option Grant, the "***Initial Grant***") with an aggregate grant date fair value of the Initial Option Grant and Initial RSU Grant of $550,000 (the "***Initial Grant Maximum Value***"), as follows:

(1) an Initial Option Grant to purchase a number of shares of common stock of the Company equal to (x) 50% of the Initial Grant Maximum Value divided by (y) the Black-Scholes value of a stock option share, determined using the average daily closing sales price per share of the Company's common stock for the thirty (30) calendar days immediately prior to the date of grant (such Black-Scholes value, the "***Average 30-Day Fair Value***"), with the resulting number rounded down to the nearest whole share; and

(2) an Initial RSU Grant with an aggregate grant date fair value, as calculated in accordance with Financial Accounting Standards Board, Accounting Standards Codification Topic 718, *Compensation—Stock Compensation* ("***FASB ASC Topic 718***"), that is equal to 50% of the Initial Grant Maximum Value, with the resulting number rounded down to the nearest whole share.

Notwithstanding the foregoing, the Board or the Compensation Committee may act prior to the Initial Award Grant Date to: (i) make an Initial Grant to any New Director with an aggregate grant date fair value that is less than the Initial Grant Maximum Value, (ii) determine to grant any New Director an Initial Grant consisting of a varying percentage of Nonstatutory Stock Options and/or RSUs (including up to 100% Nonstatutory Stock Options or 100% RSUs), and/or (iii) determine to use a methodology other than the Average 30-Day Fair Value or FASB ASC Topic 718 to calculate the shares subject to the Initial Option Grant and/or Initial RSU Grant, as applicable,

provided that the aggregate grant date fair value of the Initial Grant, as calculated in accordance with FASB ASC Topic 718, may not exceed the Initial Grant Maximum Value.

Each Initial Option Grant awarded pursuant to this Director Compensation Policy will vest in a series of 36 successive equal monthly installments over the three-year period measured from the date of grant, and each Initial RSU Grant awarded pursuant to this Director Compensation Policy will vest in a series of three successive equal annual installments over the three-year period measured from the date of grant, in each case, subject to the New Director's continued service through each applicable vesting date.

(ii) Annual Grant. Without any further action by the Board, at the close of business on the date of each Annual Meeting of the stockholders of the Company ("***Annual Award Grant Date***") following the Amendment Date, each person, other than a New Director, who is then a Non-Employee Director (a "***Continuing Director***") will automatically be granted a Nonstatutory Stock Option (an "***Annual Option Grant***") and RSUs (an "***Annual RSU Grant***", and together with the Annual Option Grant, the "***Annual Grant***") with an aggregate grant date fair value of the Annual Option Grant and Annual RSU grant of $275,000 (the "***Annual Grant Maximum Value***"), as follows:

(1) an Annual Option Grant to purchase a number of shares of common stock of the Company equal to (x) 50% of the Annual Grant Maximum Value divided by (y) the Average 30-Day Fair Value, with the resulting number rounded down to the nearest whole share; and

(2) an Annual RSU Grant with an aggregate grant date fair value, as calculated in accordance with FASB ASC Topic 718, that is equal to 50% of the Annual Grant Maximum Value, with the resulting number rounded down to the nearest whole share.

Notwithstanding the foregoing, the Board or the Compensation Committee may act prior to the Annual Award Grant Date to: (i) make an Annual Grant to any Continuing Director with an aggregate grant date fair value that is less than the Annual Grant Maximum Value, (ii) determine to grant any Continuing Director an Annual Grant consisting of a varying percentage of Nonstatutory Stock Options and/or RSUs (including up to 100% Nonstatutory Stock Options or 100% RSUs), and/or (iii) determine to use a methodology other than the Average 30-Day Fair Value or FASB ASC Topic 718 to calculate the shares subject to the Annual Option Grant and/or Annual RSU Grant, as applicable, provided that the aggregate total grant date fair value of the Annual Grant, as calculated in accordance with FASB ASC Topic 718, may not exceed the Annual Grant Maximum Value.

Each Annual Grant awarded pursuant to this Director Compensation Policy will vest at the earlier of: (i) the one-year anniversary of the date of grant, and (ii) the day immediately prior to the next Annual Meeting of the stockholders of the Company, subject to the Continuing Director's continued service through the applicable vesting date.

(b) Vesting; Change in Control. All vesting is subject to the Non-Employee Director's "***Continuous Service***" (as defined in the Plan) on each applicable vesting date. Notwithstanding the foregoing vesting schedules, for each Non-Employee Director who remains in Continuous Service with the Company until immediately prior to the closing of a "***Change in Control***" (as defined in the Plan), the shares subject to his or her then-outstanding equity awards that were granted pursuant to this Director Compensation Policy will become fully vested immediately prior to the closing of such Change in Control.

(c) Remaining Terms. The remaining terms and conditions of each award, including transferability, will be as set forth in the Company's Director Option Grant Package and Director RSU Grant Package in the forms adopted from time to time by the Board or the Compensation Committee.

Expenses

The Company will reimburse a Non-Employee Director for ordinary, necessary and reasonable out-of-pocket travel expenses to cover in-person attendance at and participation in Board and committee meetings; *provided*, that such Non-Employee Director timely submit to the Company appropriate documentation substantiating such expenses in accordance with the Company's travel and expense policy, as in effect from time to time.

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, Mark J. Gergen, J.D., certify that:

1. I have reviewed this Form 10-Q of Poseida Therapeutics, Inc.;

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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 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: August 11, 2022

By: /s/ Mark J. Gergen
Mark J. Gergen, J.D.
Chief Executive Officer
(*Principal Executive Officer*)

Exhibit 31.2

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

I, Johanna M. Mylet, C.P.A., certify that:

1. I have reviewed this Form 10-Q of Poseida Therapeutics, Inc.;

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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 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: August 11, 2022

By: /s/ Johanna M. Mylet
Johanna M. Mylet, C.P.A.
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

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Mark J. Gergen, J.D., Chief Executive Officer of Poseida Therapeutics, Inc. (the "Company") hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended June 30, 2022, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

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

Date: August 11, 2022

By: /s/ Mark J. Gergen
Mark J. Gergen, J.D.
Chief Executive Officer
(*Principal Executive Officer*)

Exhibit 32.2

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

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Johanna M. Mylet, C.P.A., Chief Financial Officer of Poseida Therapeutics, Inc. (the "Company") hereby certifies that, to the best of her knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended June 30, 2022, to which this Certification is attached as Exhibit 32.2 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

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

Date: August 11, 2022

By: /s/ Johanna M. Mylet
Johanna M. Mylet, C.P.A.
Chief Financial Officer
(*Principal Financial Officer*)