

**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 September 30, 2022

or

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

For the transition period from _____ to _____

Commission File Number: 001-39376

Poseida Therapeutics, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or Other Jurisdiction of
Incorporation or Organization)

9390 Towne Centre Drive, Suite 200, San Diego, California
(Address of Principal Executive Offices)

47-2846548
(I.R.S. Employer
Identification No.)

92121
(Zip Code)

(858) 779-3100

(Registrant's telephone number, including area code)

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

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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

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

As of November 8, 2022, the registrant had 85,949,385 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)

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 164,807	\$ 206,325
Short-term investments	114,178	—
Accounts receivable	38,467	—
Prepaid expenses and other current assets	7,677	7,548
Total current assets	325,129	213,873
Property and equipment, net	21,748	22,050
Operating lease right-of-use assets	27,000	26,177
Intangible assets	1,320	1,320
Goodwill	4,228	4,228
Other long-term assets	1,056	1,661
Total assets	\$ 380,481	\$ 269,309
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 3,426	\$ 8,961
Accrued expenses and other liabilities	22,073	23,540
Operating lease liabilities, current	6,737	6,337
Deferred revenue, current	16,732	4,497
Total current liabilities	48,968	43,335
Operating lease liabilities, non-current	25,734	25,504
Term debt	58,162	29,357
Deferred CIRM grant liability	3,992	3,992
Deferred revenue, noncurrent	25,287	9,265
Deferred tax liability	55	55
Other long-term liabilities	1,970	1,590
Total liabilities	164,168	113,098
<i>Commitments and Contingencies (Note 11)</i>		
Stockholders' equity:		
Common stock, \$0.0001 par value: 250,000,000 shares authorized at September 30, 2022 and December 31, 2021; 85,946,414 and 62,523,596 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	9	6
Additional paid-in capital	653,991	563,064
Accumulated other comprehensive loss	(144)	—
Accumulated deficit	(437,543)	(406,859)
Total stockholders' equity	216,313	156,211
Total liabilities and stockholders' equity	\$ 380,481	\$ 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 Income (Loss)
(In thousands, except share and per share amounts)
(Unaudited)

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	2022	2021	2022	2021
Revenues:				
Collaboration revenue	\$ 116,306	\$ —	\$ 120,441	\$ —
Total revenue	<u>116,306</u>	<u>—</u>	<u>120,441</u>	<u>—</u>
Operating expenses:				
Research and development	35,137	32,524	118,995	97,627
General and administrative	9,389	9,066	28,171	26,306
Total operating expenses	<u>44,526</u>	<u>41,590</u>	<u>147,166</u>	<u>123,933</u>
Income (loss) from operations	71,780	(41,590)	(26,725)	(123,933)
Other income (expense):				
Interest expense	(1,775)	(837)	(4,395)	(2,518)
Other income, net	656	3	688	8
Net income (loss) before income tax	70,661	(42,424)	(30,432)	(126,443)
Income tax expense	(252)	—	(252)	—
Net income (loss)	<u>\$ 70,409</u>	<u>\$ (42,424)</u>	<u>\$ (30,684)</u>	<u>\$ (126,443)</u>
Other comprehensive expense:				
Unrealized loss on short-term investments	(12)	(1)	(144)	(5)
Comprehensive income (loss)	<u>\$ 70,397</u>	<u>\$ (42,425)</u>	<u>\$ (30,828)</u>	<u>\$ (126,448)</u>
Net income (loss) per share, basic	<u>\$ 0.92</u>	<u>\$ (0.68)</u>	<u>\$ (0.46)</u>	<u>\$ (2.03)</u>
Net income (loss) per share, diluted	<u>\$ 0.92</u>	<u>\$ (0.68)</u>	<u>\$ (0.46)</u>	<u>\$ (2.03)</u>
Weighted-average number of shares outstanding, basic	<u>76,287,421</u>	<u>62,298,243</u>	<u>67,235,865</u>	<u>62,144,595</u>
Weighted-average number of shares outstanding, diluted	<u>76,688,382</u>	<u>62,298,243</u>	<u>67,235,865</u>	<u>62,144,595</u>

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
Issuance of common stock under employee stock compensation plans	217,688	—	540	—	—	540
Issuance of common stock from public offering, net of issuance costs of \$5,223	23,000,000	3	75,296	—	—	75,299
Stock-based compensation expense	—	—	4,277	—	—	4,277
Unrealized loss on available-for-sale investments	—	—	—	(12)	—	(12)
Net income	—	—	—	—	70,409	70,409
Balance at September 30, 2022	85,946,414	\$ 9	\$ 653,991	\$ (144)	\$ (437,543)	\$ 216,313

	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
Issuance of common stock under employee stock compensation plans	303,652	—	1,855	—	—	1,855
Stock-based compensation expense	—	—	4,151	—	—	4,151
Unrealized loss on available-for-sale investments	—	—	—	(1)	—	(1)
Net loss	—	—	—	—	(42,424)	(42,424)
Balance at September 30, 2021	62,469,819	\$ 6	\$ 558,479	\$ —	\$ (408,328)	\$ 150,157

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)

	Nine Months Ended September 30,	
	2022	2021
Operating Activities:		
Net loss	\$ (30,684)	\$ (126,443)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	3,817	3,369
Loss on disposal of property and equipment	205	3
Stock-based compensation	14,378	12,355
Accretion of discount on issued term debt	637	484
Amortization (accretion) on investment securities, net	(474)	133
Changes in operating assets and liabilities:		
Accounts receivable	(38,467)	—
Prepaid expenses and other current assets	(184)	(2,096)
Operating lease right-of-use assets	3,602	2,699
Other long-term assets	606	(228)
Accounts payable	(5,536)	2,882
Accrued expenses and other liabilities	(1,536)	(1,906)
Operating lease liabilities	(3,796)	(2,268)
Deferred revenue	28,257	—
Net cash used in operating activities	<u>(29,175)</u>	<u>(111,016)</u>
Investing Activities:		
Purchases of property and equipment	(3,664)	(2,421)
Proceeds from sale of property and equipment	12	—
Purchases of short-term investments	(143,792)	—
Proceeds from maturities of short-term investments	30,000	225,000
Net cash provided by (used in) investing activities	<u>(117,444)</u>	<u>222,579</u>
Financing Activities:		
Net proceeds from issuance of common stock under employee stock compensation plans	1,252	2,282
Proceeds from public offering of common stock, net of issuance costs	75,299	—
Payment of debt issuance costs	(1,450)	—
Proceeds from term debt	30,000	—
Net cash provided by financing activities	<u>105,101</u>	<u>2,282</u>
Net increase (decrease) in cash and cash equivalents	(41,518)	113,845
Cash and cash equivalents at beginning of period	206,325	83,966
Cash and cash equivalents at end of period	<u>\$ 164,807</u>	<u>\$ 197,811</u>
Non-cash operating, investing and financing activities:		
Purchases of property and equipment in accounts payable and accrued liabilities	\$ 68	\$ 58
Deferred offering costs incurred but not yet paid	\$ —	\$ 115
Supplemental disclosure of cash flow information:		
Interest paid	\$ 3,470	\$ 2,041

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 cell and gene therapy company advancing a new class of treatments for patients with cancer and rare diseases. 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 strategic collaborations. For the nine months ended September 30, 2022, the Company incurred a net loss of \$30.7 million and negative cash flows from operations of \$29.2 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 September 30, 2022, the Company had an accumulated deficit of \$437.5 million.

The Company expects that its cash, cash equivalents and short-term investments as of September 30, 2022 of \$279.0 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. 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 two customers. 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. The Company allocates the transaction price to individual performance obligations on their relative standalone selling price basis. Standalone selling prices are based on observable prices at which the Company separately sells the products or services. If a standalone selling price is not directly observable, then the Company estimates the standalone selling price considering market conditions and entity-specific factors including, but not limited to, features and functionality of the products and services.

The Company receives payments from its collaborators based on terms established in each contract. Upfront payments and other payments may require deferral of revenue recognition to a future period until the Company satisfies its performance obligations under the contract.

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 September 30, 2022 and December 31, 2021, the Company recorded no allowance for credit losses.

Comprehensive Income (Loss)

Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources, including unrealized gains and losses on short-term investments. Comprehensive gains (losses) have been reflected in the unaudited condensed consolidated statements of operations and comprehensive income (loss) for all periods presented.

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):

	September 30, 2022	December 31, 2021
Laboratory equipment	\$ 17,312	\$ 14,192
Leasehold improvements	14,007	13,910
Computer equipment and software	2,263	2,137
Furniture, fixtures and other	997	948
Total property and equipment	34,579	31,187
Less: Accumulated depreciation and amortization	(12,831)	(9,137)
Total property and equipment, net	<u>\$ 21,748</u>	<u>\$ 22,050</u>

Depreciation and amortization expense associated with property and equipment was \$1.4 million and \$3.8 million for the three and nine months ended September 30, 2022, respectively and \$1.2 million and \$3.4 million for the three and nine months ended September 30, 2021, respectively.

Accrued expenses and other liabilities

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

	September 30, 2022	December 31, 2021
Contract research services	\$ 11,094	\$ 12,292
Payroll and related expense	7,504	8,760
Other	3,475	2,488
Total accrued expenses and other liabilities	<u>\$ 22,073</u>	<u>\$ 23,540</u>

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
September 30, 2022:				
Money market fund	\$ 37,644	\$ —	\$ —	\$ 37,644
U.S. government agency securities and treasuries	114,322	1	(145)	114,178
Total	<u>\$ 151,966</u>	<u>\$ 1</u>	<u>\$ (145)</u>	<u>\$ 151,822</u>
December 31, 2021:				
Money market fund	\$ 176,102	\$ —	\$ —	\$ 176,102
Total	<u>\$ 176,102</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 176,102</u>

No available-for-sale debt securities held as of September 30, 2022 and December 31, 2021 had remaining maturities greater than one year. At September 30, 2022, the Company did not have any securities in material unrealized loss positions.

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
September 30, 2022:			
Assets:			
Money market funds and U.S. government agency treasuries(1)	\$ 37,644	\$ —	\$ —
Short-term investments	114,178	—	—
Total	<u>\$ 151,822</u>	<u>\$ —</u>	<u>\$ —</u>
December 31, 2021:			
Assets:			
Money market funds(1)	\$ 176,102	\$ —	\$ —
Total	<u>\$ 176,102</u>	<u>\$ —</u>	<u>\$ —</u>

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

Note 6. Collaboration and License Agreements

Roche

Terms of the Agreement

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 the Company granted 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. The Roche Collaboration Agreement became effective in September 2022 upon expiration of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended.

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.

In consideration for the rights granted to Roche under the Roche Collaboration Agreement, the Company received an upfront payment of \$110.0 million. In addition, subject to Roche exercising its Tier 2 Program options, designating Collaboration Programs, and exercising its option for the Licensed Products commercial license and further contingent on, among other things, achieving specified objectives, the Company is eligible to receive up to (i) \$1.5 billion in aggregate payments for Tier 1 Programs comprised of research funding, feasibility fees and \$1.4 billion in development, regulatory and net sales milestones, (ii) \$1.1 billion in aggregate payments for Tier 2 Programs comprised of option exercise and maintenance fees and \$1.0 billion in development, regulatory and net sales milestones, (iii) \$2.9 billion in aggregate payments for the Collaboration Programs comprised of certain reimbursements, fees and milestone payments; and (iv) \$415.0 million in payments for the Licensed Products comprised of certain reimbursements, fees and milestone payments.

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 continue in effect 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.

Revenue Recognition

At contract inception, the Company has identified six performance obligations under the Roche Collaboration Agreement: (i) licenses associated with the Tier 1 Programs, (ii) research and development efforts for the Tier 1 Programs, (iii) clinical drug supply for the Tier 1 Programs, (iv) manufacturing process development program for the Tier 1 Programs, (v) research and development efforts for the Tier 2 programs, and (vi) research and development efforts for the Collaboration Programs. The Company concluded that Roche's options within the Roche Collaboration Agreement do not represent material rights and are not considered performance obligations as they do not contain a significant and incremental discount.

In order to determine the transaction price, the Company evaluated all the payments to be received during the term of the Roche Collaboration Agreement. Certain milestones and additional fees were considered variable consideration, which were not included in the initial transaction price based on the most likely amount method. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur. The Company determined that the transaction price at the inception of the Roche Collaboration Agreement was \$185.0 million, which consists of the upfront payment of \$110.0 million, future research funding for the Tier 1 Programs of \$40.0 million and a \$35.0 million milestone achieved in September 2022 for the Tier 1 Programs. As of September 30, 2022, all other future potential milestone payments were excluded from the estimated total transaction price as they were considered constrained.

The performance obligation associated with the licenses for the Tier 1 Programs was satisfied as of the effective date of the Roche Collaboration Agreement. All other performance obligations will be recognized on a proportional basis as the underlying services are provided based on actual costs incurred as a percentage of total estimated costs. The Company determined that the cost-based input method most faithfully depicts the pattern in which these performance obligations are satisfied. Any cumulative effect of revisions to estimated costs to complete the Company's performance obligation will be recorded in the period in which changes are identified and amounts can be reasonably estimated. This approach requires the Company to use significant judgement and make estimates of future expenditures. If the Company's estimates or judgements change over the course of the collaboration, they may affect the timing and amount of revenue that it recognizes in the current and future periods.

Takeda

Terms of the Agreement

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.

Revenue Recognition

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, which are delivered over time, 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 September 30, 2022, all future potential milestone payments were excluded from the estimated total transaction price as they were considered constrained.

There are no contract assets as of September 30, 2022 or December 31, 2021 related to the Roche Collaboration Agreement or Takeda Collaboration Agreement. A reconciliation of the closing balance of deferred revenue related to the agreements is as follows (in thousands):

	<u>Roche Collaboration Agreement</u>	<u>Takeda Collaboration Agreement</u>	<u>Total</u>
Balance as of December 31, 2020	\$ —	\$ —	\$ —
Amounts received/invoiced	—	45,000	45,000
Revenue recognized	—	(31,238)	(31,238)
Balance as of December 31, 2021	\$ —	\$ 13,762	\$ 13,762
Amounts received/invoiced	146,533	2,165	148,698
Revenue recognized	(114,109)	(6,332)	(120,441)
Balance as of September 30, 2022	<u>\$ 32,424</u>	<u>\$ 9,595</u>	<u>\$ 42,019</u>

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. In September 2022, a qualifying equity event, as defined in the 2022 Loan Agreement, was achieved which extended the interest-only period 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 September 30, 2022 was 10.38% 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 September 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 12.05%. As of September 30, 2022, the balance of the unamortized debt discount was \$1.8 million. The balance of the accrued final payment fee was \$2.0 million as of September 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 September 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.

Sale of Common Stock

In August 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.

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 nine months ended September 30, 2022:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (thousands)
Balance at January 1, 2022	9,899,707	\$ 9.57		
Granted	3,725,101	3.67		
Exercised	(94,164)	1.44		
Forfeited/Cancelled	(1,567,282)	9.12		
Balance at September 30, 2022	11,963,362	\$ 7.85	8.39	\$ 1,409
Options vested and expected to vest as of September 30, 2022	11,963,362	\$ 7.85	8.39	\$ 1,409
Options vested and exercisable as of September 30, 2022	4,720,812	\$ 9.24	7.70	\$ 619

The weighted-average grant date fair value of options granted during the nine months ended September 30, 2022 and 2021 was \$2.63 and \$6.32, respectively. The aggregate intrinsic value of options exercised during the nine months ended September 30, 2022 and 2021 was \$0.1 million and \$3.2 million, respectively, determined as of the date of exercise. The Company received \$0.1 million and \$1.7 million in cash from options exercised during the nine months ended September 30, 2022 and 2021, respectively.

As of September 30, 2022, total unrecognized compensation cost related to stock options was \$34.0 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:

	Nine Months Ended September 30,	
	2022	2021
Risk-free interest rate	1.3%–3.4%	0.5%–1.1%
Expected volatility	83.0%–92.2%	82.2%–84.3%
Expected term (years)	3.0–6.0	5.5–6.0
Dividend yield	—	—

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

	Shares	Weighted Average Grant Date Fair Value
Balance at January 1, 2022	—	\$ —
Granted	2,594,471	3.67
Vested	—	—
Forfeited/Cancelled	(221,544)	3.52
Balance at September 30, 2022	<u>2,372,927</u>	<u>\$ 3.68</u>

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 September 30, 2022, total unrecognized compensation cost related to RSUs was \$7.4 million, and the weighted-average period over which this cost is expected to be recognized was approximately 3.3 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 lesser 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 nine months ended September 30, 2022, a total of 328,654 shares were purchased by the Company's employees under the 2020 ESPP resulting in net proceeds of \$1.1 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 nine months ended September 30, 2022 and 2021 were as follows:

	Nine Months Ended September 30,	
	2022	2021
Risk-free interest rate	0.6% - 3.9%	0.1%
Expected volatility	84.4 - 101.5%	74.8 - 87.9%
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 income (loss) (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Research and development	\$ 2,056	\$ 2,049	\$ 7,132	\$ 5,966
General and administrative	2,221	2,102	7,246	6,389
Total stock-based compensation expense	<u>\$ 4,277</u>	<u>\$ 4,151</u>	<u>\$ 14,378</u>	<u>\$ 12,355</u>

Note 11. Commitments and Contingencies

Operating Leases

As of September 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 7.3 years. During the nine months ended September 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 1.3 years.

During the nine months ended September 30, 2022 and 2021, the Company recognized \$5.4 million and \$4.7 million, respectively, of operating lease expense, including a \$0.6 million impairment of an ROU asset during the nine months ended September 30, 2022. During the nine months ended September 30, 2022, the Company paid \$6.1 million for its operating leases. As of September 30, 2022, the weighted-average remaining lease term and weighted-average discount rate for operating leases were 6.5 years and 8.9%, respectively.

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

<u>Year ending December 31,</u>	
2022 (remaining 3 months)	\$ 1,729
2023	7,057
2024	6,188
2025	6,374
2026	5,107
Thereafter	16,260
Total future lease payments	42,715
Imputed interest	(10,244)
Total lease liability balance	32,471
Less current portion of lease liability	6,737
Lease liability, net of current portion	<u>\$ 25,734</u>

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 Income (Loss) Per Share

Basic net income (loss) per share is computed by dividing net income (loss) attributable to common stockholders for the period by the weighted-average number of common shares outstanding during the period. Diluted net income (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 following table sets for the computation of basic and diluted net income (loss) per share (in thousands, except share and per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Numerator:				
Net income (loss)	\$ 70,409	\$ (42,424)	\$ (30,684)	\$ (126,443)
Numerator for basic and diluted net income (loss) per share stockholders	<u>\$ 70,409</u>	<u>\$ (42,424)</u>	<u>\$ (30,684)</u>	<u>\$ (126,443)</u>
Denominator:				
Denominator for basic net income (loss) per share - weighted-average common stock outstanding	76,287,421	62,298,243	67,235,865	62,144,595
Effect of dilutive securities:				
Common stock options	147,443	—	—	—
RSUs	237,212	—	—	—
ESPP shares	16,306	—	—	—
Denominator for diluted net income (loss) per share - adjusted weighted-average common stock outstanding	<u>76,688,382</u>	<u>62,298,243</u>	<u>67,235,865</u>	<u>62,144,595</u>
Basic net income (loss) per share	\$ 0.92	\$ (0.68)	\$ (0.46)	\$ (2.03)
Diluted net income (loss) per share	\$ 0.92	\$ (0.68)	\$ (0.46)	\$ (2.03)

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:

	Nine Months Ended September 30,	
	2022	2021
Outstanding stock options and RSUs	14,336,289	8,456,838
Warrants to purchase common stock	121,122	121,122
	<u>14,457,411</u>	<u>8,577,960</u>

Note 13. Income Taxes

Beginning in 2022, the Tax Cuts and Jobs Act of 2017 requires taxpayers to capitalize and amortize research and development expenditures over five years for domestic research and 15 years for foreign research pursuant to Section 174 of the Internal Revenue Code of 1986, as amended. Although the U.S. Congress is considering legislation that would defer the amortization requirement to later years, the Company has no assurance that the provision will be repealed or otherwise modified. As a result, the Company recorded income tax expense of \$0.3 million for the three and nine months ended September 30, 2022. Additionally, the Company's effective tax rate for the three and nine months ended September 30, 2022, was 0.4% and (0.8)%, respectively. This rate differed from the federal tax rate of 21% primarily due to the inability to benefit the Company's financial reporting loss for income tax purposes, as well as the limitation on the use of previously unbenefited tax losses and credits carried forward from prior years to fully offset current year taxable income resulting from the requirement to capitalize research and development costs for federal income tax purposes.

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 cell and gene therapy company advancing a new class of treatments for patients with cancer and rare diseases. 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 with an emphasis on allogeneic. 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 a new class of 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-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. P-MUC1C-ALLO1 is the first program for which clinical product is sourced from our internal pilot manufacturing facility. We are currently evaluating P-MUC1C-ALLO1 in a Phase 1 clinical trial and we plan to share an initial clinical data update on the program at the European Society for Medical Oncology Immuno-Oncology 2022 Annual Congress, or ESMO I-O, which is taking place in Geneva, Switzerland and online in December 2022.
- **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 have been evaluating P-PSMA-101 in a Phase 1 trial, however we have made the strategic decision to stop further enrollment. The clinical data from the Phase 1 trial is still being collected and analyzed and will be utilized to inform other solid tumor allogeneic programs, including our preclinical allogeneic program, P-PSMA-ALLO1.
- **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 plan to share an initial clinical data update on the program at the ESMO I-O, 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.

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 are developing 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 plan to present preclinical data from this program at the 64th American Society of Hematology (ASH) Annual Meeting and Exposition being held in New Orleans, Louisiana and online in December 2022.

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-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-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 granted 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 paid an upfront payment to us of \$110.0 million. 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) \$415.0 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 became effective in September 2022 upon the expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and will 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.

- 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 agreements with Roche and Takeda and reflects the timing and pattern in which we deliver the contractual deliverables to our partners.

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 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-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. Given the environment of increasing interest rates, we expect our interest expense to increase incrementally to reflect market rates.

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 September 30, 2022 and 2021

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

	Three Months Ended September 30,		Change
	2022	2021	
Revenues:			
Collaboration revenue	\$ 116,306	\$ —	\$ 116,306
Total revenue	116,306	—	116,306
Operating expenses:			
Research and development	35,137	32,524	2,613
General and administrative	9,389	9,066	323
Total operating expenses	44,526	41,590	2,936
Income (loss) from operations	71,780	(41,590)	113,370
Other income (expense):			
Interest expense	(1,775)	(837)	(938)
Other income (expense), net	656	3	653
Net income (loss) before income tax	70,661	(42,424)	113,085
Income tax expense	(252)	—	(252)
Net income (loss)	\$ 70,409	\$ (42,424)	\$ 112,833

Collaboration Revenue

Collaboration revenue of \$116.3 million for the three months ended September 30, 2022 represents revenue recognized from the research services performed under the Takeda Collaboration Agreement that we entered into in the fourth quarter of 2021 and the Roche Collaboration Agreement which became effective in the third quarter of 2022.

Research and Development Expenses

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

	Three Months Ended September 30,		Change
	2022	2021	
External costs:			
Clinical stage programs ⁽¹⁾	\$ 8,630	\$ 10,151	\$ (1,521)
Preclinical stage programs and other unallocated expenses	7,570	8,317	(747)
Internal costs:			
Personnel	15,010	11,200	3,810
Facilities and other	3,927	2,856	1,071
Total research and development expenses	<u>\$ 35,137</u>	<u>\$ 32,524</u>	<u>\$ 2,613</u>

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

Research and development expenses were \$35.1 million for the three months ended September 30, 2022, compared to \$32.5 million for the three months ended September 30, 2021. The increase in research and development expenses of \$2.6 million was primarily due to an increase of \$3.8 million in personnel expenses as a result of increased headcount and an increase of \$1.1 million in facilities expense, offset by a decrease of \$1.5 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, 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 \$0.7 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.

General and Administrative Expenses

General and administrative expenses were \$9.4 million for the three months ended September 30, 2022, compared to \$9.1 million for the three months ended September 30, 2021. The increase in general and administrative expenses of \$0.3 million was primarily due to an increase of \$0.3 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 \$1.8 million for the three months ended September 30, 2022, compared to \$0.8 million for the three months ended September 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 \$0.9 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 \$0.7 million for the three months ended September 30, 2022, compared to less than \$0.1 million for the three months ended September 30, 2021. The increase in other income, net of \$0.7 million was driven by an increase in interest income, as a result of higher interest rates available and a higher cash balance in the respective periods.

Comparison of the Nine Months Ended September 30, 2022 and 2021

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

	Nine Months Ended September 30,		Change
	2022	2021	
Revenues:			
Collaboration revenue	\$ 120,441	\$ —	\$ 120,441
Total revenue	120,441	—	120,441
Operating expenses:			
Research and development	118,995	97,627	21,368
General and administrative	28,171	26,306	1,865
Total operating expenses	147,166	123,933	23,233
Loss from operations	(26,725)	(123,933)	97,208
Other income (expense):			
Interest expense	(4,395)	(2,518)	(1,877)
Other income (expense), net	688	8	680
Net loss before income tax	(30,432)	(126,443)	96,011
Income tax expense	(252)	—	(252)
Net loss	<u>\$ (30,684)</u>	<u>\$ (126,443)</u>	<u>\$ 95,759</u>

Collaboration Revenue

Collaboration revenue of \$120.4 million for the nine months ended September 30, 2022 represents revenue recognized from the research services performed under the Takeda Collaboration Agreement that we entered into in the fourth quarter of 2021 and the Roche Collaboration Agreement which became effective in the third quarter of 2022.

Research and Development Expenses

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

	Nine Months Ended September 30,		Change
	2022	2021	
External costs:			
Clinical stage programs ⁽¹⁾	\$ 40,287	\$ 33,098	\$ 7,189
Preclinical stage programs and other unallocated expenses	23,391	23,776	(385)
Internal costs:			
Personnel	44,419	32,192	12,227
Facilities and other	10,898	8,561	2,337
Total research and development expenses	<u>\$ 118,995</u>	<u>\$ 97,627</u>	<u>\$ 21,368</u>

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

Research and development expenses were \$119.0 million for the nine months ended September 30, 2022, compared to \$97.6 million for the nine months ended September 30, 2021. The increase in research and development expenses of \$21.4 million was primarily due to an increase of \$12.2 million in personnel expenses as a result of an increase in headcount which included a \$1.1 million increase in stock-based compensation expense, an increase of \$7.2 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, and a \$2.3 million increase in internal facilities and other costs, offset by a \$0.4 million decrease in preclinical stage programs and other unallocated expenses. The increase in external costs related to our clinical stage programs is partially offset by the wind-down of our clinical development activities associated with the P-BCMA-101 program. The increase in facility and other of \$2.3 million was primarily due to an additional lease entered into in 2022 to support continued headcount growth.

General and Administrative Expenses

General and administrative expenses were \$28.2 million for the nine months ended September 30, 2022, compared to \$26.3 million for the nine months ended September 30, 2021. The increase in general and administrative expenses of \$1.9 million was primarily due to an increase of \$1.6 million in personnel expenses as a result of an increase in headcount which included a \$0.9 million increase in stock-based compensation expense, and a \$0.3 million increase in legal and other professional fees.

Interest Expense

Interest expense was \$4.4 million for the nine months ended September 30, 2022, compared to \$2.5 million for the nine months ended September 30, 2021 and consisted of interest on the principal balance outstanding under our term loans with Oxford. The increase in interest expense of \$1.9 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 \$0.7 million and zero for the nine months ended September 30, 2022 and 2021, respectively, and was primarily due to increased interest rates and higher balances on cash, cash equivalents and short-term investments.

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 strategic collaborations. For the nine months ended September 30, 2022 we have incurred a net loss of \$30.7 million, and negative cash flows from operations of \$29.2 million. We expect to continue to incur net losses and negative cash flows from operations for at least the next several years. As of September 30, 2022, we had an accumulated deficit of \$437.5 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 strategic collaborations. Since our inception, we have raised \$304.5 million of gross proceeds from the sale of our common stock in our public offerings, \$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 September 2022, the Roche Collaboration Agreement became effective and Roche paid an upfront payment to us of \$110.0 million and we earned an additional \$35.0 million in milestone revenue.

We expect that our cash, cash equivalents and short-term investments as of September 30, 2022, of \$279.0 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. In September 2022, a qualifying equity event, as defined in the Amended Loan Agreement, was achieved which extended the interest-only period 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 September 30, 2022, the interest rate applicable to our Term Loans borrowing was 10.38%.

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):

	Nine Months Ended September 30,	
	2022	2021
Cash used in operating activities	\$ (29,175)	\$ (111,016)
Cash provided by (used in) investing activities	(117,444)	222,579
Cash provided by financing activities	105,101	2,282
Net increase (decrease) in cash and cash equivalents	\$ (41,518)	\$ 113,845

Cash Used in Operating Activities

During the nine months ended September 30, 2022, net cash used in operating activities was \$29.2 million, primarily resulting from our net loss of \$30.7 million and a net cash decrease from changes in our operating assets and liabilities of \$17.1 million, partially offset by non-cash expenses of \$18.6 million. Net cash decrease from changes in our operating assets and liabilities for the nine months ended September 30, 2022 consisted primarily of a \$38.5 million increase in accounts receivable and decreases of \$5.5 million in accounts payable, \$3.8 million in operating lease liabilities and \$1.5 million in accrued expenses and other liabilities, partially offset by a \$28.3 million increase in deferred revenue and a \$3.6 million decrease in operating lease right-of-use assets. Non-cash charges consisted primarily of \$14.4 million in stock-based compensation, \$3.8 million in depreciation and amortization expense, \$0.6 million in accretion of discount on issued term debt, and \$0.2 million from loss on disposal of property and equipment, partially offset by \$0.5 million in accretion on investment securities, net.

During the nine months ended September 30, 2021, net cash used in operating activities was \$111.0 million, primarily resulting from our net loss of \$126.4 million, combined with non-cash expenses of \$16.3 million, and net cash decrease from changes in our operating assets and liabilities of \$0.9 million. Non-cash charges consisted primarily of \$12.4 million in stock-based compensation and \$3.4 million in depreciation and amortization expense. Net cash decrease from changes in our operating assets and liabilities for

the nine months ended September 30, 2021 consisted primarily of a \$2.1 million increase in prepaid expenses and other current assets and by a \$1.9 million decrease in accrued expenses and other liabilities, partially offset by a \$2.9 million increase in accounts payable.

Cash Provided by (Used in) Investing Activities

During the nine months ended September 30, 2022, cash used in investing activities was \$117.4 million, consisting of \$143.8 million in purchases of short-term investments and \$3.6 million in purchases of property and equipment, partially offset by \$30.0 million in proceeds from maturities of short-term investments.

During the nine months ended September 30, 2021, net cash provided by investing activities was \$222.6 million, consisting primarily of proceeds from maturities of short-term investments of \$225.0 million, partially offset by purchases of property and equipment of \$2.4 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 nine months ended September 30, 2022, net cash provided by financing activities was \$105.1 million, consisting of \$75.3 million of net proceeds from our public offering of common stock, \$28.6 million of proceeds from the 2022 Loan Agreement, net of debt issuance costs and repayment of the Amended Loan Agreement, and \$1.3 million of proceeds from purchases under our ESPP and exercises of stock options.

During the nine months ended September 30, 2021, net cash provided by financings activities was \$2.3 million, representing proceeds from the exercises of stock options and purchases under our 2020 Employee Stock Purchase Plan.

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 nine months ended September 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 revenue recognition, 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 nine months ended September 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 us 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 \$1.235 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 September 30, 2022, we had cash, cash equivalents and short-term investments of \$279.0 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 September 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 September 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 September 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 cell and gene therapy 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 cell and gene therapy 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 cell and gene therapy 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 nine months ended September 30, 2022 and 2021, we have incurred a net loss of \$30.7 million and \$126.4 million, respectively. As of September 30, 2022, we had an accumulated deficit of \$437.5 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 September 30, 2022, we had \$279.0 million in cash, cash equivalents and short-term investments. Based upon our current operating plan, we believe that our existing cash and cash equivalents 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 OfferingSM 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, or 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. In November 2022, we announced the decision to wind down clinical development of our P-PSMA-101 program, our first solid tumor clinical trial. We 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, P-PSMA-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 did not yet impact 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 resumed the trial, reporting 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 other trials 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-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 München —Deutsches Forschungszentrum für 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 United 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 \$10.0 million per occurrence and \$10.0 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 September 30, 2022, we had 304 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 \$23.0 million of U.S. federal NOLs that will begin to expire in 2032, and \$330.5 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. 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. On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the “donut hole” under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program. It is unclear how any additional 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 including the Infrastructure Investment and Jobs Act, the BBA and the Coronavirus Aid, Relief, and Economic Security Act, will remain in effect through 2031 unless additional Congressional action is taken. These reductions were 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 4% 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. 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, the Department of Health and Human Services, or 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. In addition, the IRA, among other things, (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated “maximum fair price” for such drugs and biologics under the law, and (ii) imposes rebates with respect to certain drugs and biologics covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry.

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 November 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 November 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 November 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, process, 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 and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties upon which we rely. These threats are prevalent, continue to increase, and 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. Some threat actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations.

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. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies.

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. If our third-party service providers experience a security incident or other interruption, we could also experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award.

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 whom 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 to 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.

**** We are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security. Our actual or perceived 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, fines and penalties, disruptions of our business operations, reputational harm, loss of revenue or profits, 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, there are 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) and allows private litigants affected by certain data breaches to recover significant statutory damages. 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 and extends the applicability of the CCPA's requirements to personal information of business representatives and employees. 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 and may increase legal risk and compliance costs for us and the third parties upon whom we rely. 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, Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (EEA) and the United Kingdom (UK) have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA and UK's standard contractual clauses, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Some European regulators have prevented companies from transferring personal data out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

We may also be bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, certain privacy laws, such as the GDPR and the CCPA, require our customers to impose specific contractual restrictions on their service providers. We may publish privacy policies, marketing materials and other

statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Obligations related to data privacy and security are quickly changing, becoming increasingly stringent, and creating regulatory uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources. These obligations may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. 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 substantial changes to our business model or 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 \$1.235 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 September 30, 2022, we have used approximately \$189.4 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	<u>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).</u>
3.2	<u>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).</u>
4.1	<u>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).</u>
4.2	<u>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).</u>
4.3	<u>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).</u>
4.4	<u>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).</u>
4.5	<u>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).</u>
10.1 [^]	<u>Collaboration and License Agreement, dated July 30, 2022, by and among the Registrant, F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc.</u>
31.1	<u>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.</u>
31.2	<u>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.</u>
32.1*	<u>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.</u>
32.2*	<u>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.</u>
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)

[^] Pursuant to Item 601(b)(10) of Regulation S-K, certain portions of this exhibit have been omitted by means of marking such portions with asterisks because the information is both not material and is the type that the Registrant treats as private or confidential.

* 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.

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: November 10, 2022

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

Date: November 10, 2022

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

CERTAIN INFORMATION CONTAINED IN THIS EXHIBIT, MARKED BY [***], HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE THE REGISTRANT HAS DETERMINED THAT IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

CONFIDENTIAL
EXECUTION VERSION

**COLLABORATION AND LICENSE AGREEMENT BETWEEN
POSEIDA THERAPEUTICS, INC. AND
F. HOFFMANN-LA ROCHE LTD AND HOFFMANN-LA ROCHE INC. AS OF
JULY 30, 2022**

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EXHIBITS

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[***] = Certain Confidential Information Omitted

COLLABORATION AND LICENSE AGREEMENT

THIS COLLABORATION AND LICENSE AGREEMENT (“Agreement”) is made and entered into, as of July 30, 2022 (“**Execution Date**”), between Poseida Therapeutics, Inc., a Delaware corporation, having its principal place of business at 9390 Towne Centre Dr. #200, San Diego, CA 92121, United States of America (“**Poseida**”), on the one hand, and F. Hoffmann-La Roche Ltd, having its principal place of business at Grenzacherstrasse 124, CH 4070 Basel, Switzerland (“**FHLR**”) and Hoffmann-La Roche Inc., having its principal place of business at 150 Clove Rd., Suite 8, Little Falls, NJ 07424, United States of America (“**HLR**”; FHLR and HLR together referred to as “**Roche**”), on the other hand. Poseida and Roche are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**.”

BACKGROUND

WHEREAS, Poseida is a biotechnology company that researches and develops allogeneic CAR T-cell therapeutic products and has expertise in gene delivery and gene editing technologies.

WHEREAS, Roche is a biopharmaceutical company that is engaged in the research, development, manufacture and sale of pharmaceutical products.

WHEREAS, Poseida desires to grant to Roche an exclusive license to certain allogeneic CAR T- cell therapeutic products and an option to exclusively license certain other allogeneic CAR T-cell therapeutic products, which Roche would develop and commercialize.

WHEREAS, Poseida and Roche desire to collaborate in the research of improvements to CAR T- cell therapy and the research of novel allogeneic CAR T-cell therapeutic products, which Roche would develop and commercialize.

WHEREAS, Poseida desires to grant to Roche a non-exclusive license and sublicense to certain technologies for Roche to use and incorporate in the research, development, and commercialization of TCR-expressing cell therapeutic products.

NOW THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, Roche and Poseida agree as follows:

ARTICLE 1 Definitions

Capitalized terms used in this Agreement, whether used in the singular or plural, shall have the meanings set forth below, unless otherwise specifically indicated herein.

1.1 “**Accounting Standards**” means the maintenance of records and books of accounts in accordance with either International Financial Reporting Standards or US Generally Accepted Accounting Principles, in each case as currently used at the applicable time by, and as consistently applied by, the applicable Party or its Affiliate or Sublicensee.

1.2 “Acquirer” is defined in Section 6.11.

1.3 “Acquisition Affiliate” is defined in Section 7.2.2.

1.4 “Active Program” means, with respect to a Target, a research or preclinical or clinical development program Directed To such Target, including such program that is conducted by Poseida or its Affiliates outside of this Agreement, with respect to which (a) (i) [***]; and (ii) Poseida, together with its Affiliates, spent at least [***] on such program, during the preceding [***].

- 1.5 “Additional Collaboration Research Fee” is defined in Section 8.4.1.

- 1.6 “Additional Collaboration Research Plan” is defined in Section 3.4.2.

- 1.7 “Additional Collaboration Research Program” is defined in Section 3.4.2.

- 1.8 “Additional Collaboration Research Project” is defined in Section 3.4.2.

- 1.9 “Additional Collaboration Research Term” is defined in Section 3.4.2.

- 1.10 [***].

- 1.11 “Additional Existing Programs” means each of (a) Poseida’s program for the research and development of an Allo CAR T-Cell Therapy [***] for the treatment of Heme Malignancies including [***], and (b) Poseida’s program for the research and development of an Allo CAR T- Cell [***] for the treatment of Heme Malignancies, including [***].

1.12 “Affiliate” means any entity that, directly or indirectly (through one or more intermediaries) controls, is controlled by, or is under common control with a Party, at any point in time and for so long as such control exists. For purposes of the preceding sentence, “controls”, “controlled”, and “control” means (i) the direct or indirect ownership of more than fifty percent (>50%) of the voting stock or other voting interests or interest in the profits of the Party, or (ii) the ability to otherwise control or direct the decisions of the board of directors or equivalent governing body thereof. [***]

[***] = Certain Confidential Information Omitted

[***].

1.13 “**Alliance Manager**” is defined in Section 2.7.

1.14 “**Allo CAR T-Cell Therapy**” means [***].

1.15 “**Allogeneic Licensed Product**” means [***].

1.16 “**Annual Net Sales**” means, with respect to a Therapeutic Product or Licensed Product, as applicable, all Net Sales of such Therapeutic Product or Licensed Product, as applicable, during a Calendar Year.

1.17 “**Antigen Binder**” means, with respect to a CAR or CAR Cell, the antigen recognition domains of any and all proteins, protein fragments, or peptides (including full-length antibodies, heavy chain-only antibodies (including VH or VHH), nanobodies, antigen-binding fragments (Fabs), and single-chain variable domain fragments (scFvs)) included in such CAR or expressed by such CAR Cell that bind, or contribute to the binding, to a Target.

1.18 “**Authorized Subcontractors**” means, [***], the Poseida subcontractors (a) [***] or (b) [***].

1.19 “**Autologous Licensed Product**” means [***].

1.20 “**Available Target**” means [***].

1.21 “[***]” is defined in Section 3.4.4(a).

1.22 “**Biosimilar Product**” means, with respect to a Therapeutic Product in a country or jurisdiction worldwide, [***]

[***] = Certain Confidential Information Omitted

[***].

1.23 “**Board of Directors**” is defined in Section 1.33(a).

1.24 “**Business Day**” means any day, other than a Saturday, Sunday or day on which commercial banks located in Switzerland or San Diego, California (US) are authorized or required by law to be closed.

1.25 “**Calendar Quarter**” means each successive period of three (3) calendar months commencing on January 1, April 1, July 1 or October 1, except that the first Calendar Quarter of the Term shall commence on the Effective Date and end on the day immediately prior to the first to occur of January 1, April 1, July 1 or October 1 after the Effective Date, and the last Calendar Quarter of the Term shall end on the last day of the Term.

1.26 “**Calendar Year**” means each successive period of twelve (12) calendar months commencing on January 1 and ending on December 31, except that the first Calendar Year of the Term shall commence on the Effective Date and end on December 31 of the year in which the Effective Date occurs and the last Calendar Year of the Term shall commence on January 1 of the year in which the Term ends and end on the last day of the Term.

1.27 “**CAR**” means a chimeric antigen receptor.

1.28 “**CAR Cell**” means a T-cell expressing a construct encoding the nucleotide sequence of at least one (1) CAR that includes an extracellular domain (including an Antigen Binder), a transmembrane domain, and a cytosolic signaling domain.

1.29 “**Cas-CLOVER Gene Editing IP**” means (a) all Know-How comprising Cas-CLOVER Gene Editing Technology and (b) all Patents claiming any such Know-How or otherwise Covering any Cas-CLOVER Gene Editing Technology, in each case (a) and (b), Controlled by Poseida or its Affiliates as of the Execution Date or at any time thereafter until the end of the Term. The Patents in clause (b) existing as of the Execution Date are listed on Exhibit 1.29.

1.30 “**Cas-CLOVER Gene Editing Technology**” means [***].

1.31 “**Cell Therapy**” means a pharmaceutical product comprising living cells that are administered to a patient and intended to treat, cure, or prevent a disease or condition.

1.32 “**Challenge**” is defined in Section 12.10.1.

1.33 “**Change in Control**” with respect to Poseida, shall be deemed to have occurred if any of the following occurs after the Effective Date:

[***] = Certain Confidential Information Omitted

(a) any “person” or “group” (as such terms are defined below) (i) becomes the “beneficial owner” (as defined below), directly or indirectly, of shares of capital stock or other interests (including partnership interests) then-outstanding and normally entitled (without regard to the occurrence of any contingency) to vote in the election of the directors, managers or similar supervisory positions (“**Voting Stock**”) of Poseida representing more than fifty percent (>50%) of the total voting power of all outstanding classes of Voting Stock of Poseida or (ii) acquires the power, directly or indirectly, to elect a majority of the members of the board of directors or similar governing body (“**Board of Directors**”) of Poseida; or

(b) Poseida enters into a merger, consolidation or similar transaction with a Third Party (whether or not Poseida is the surviving entity) and as a result of such merger, consolidation or similar transaction (i) the members of the Board of Directors of Poseida immediately prior to such transaction constitute less than a majority of the members of the Board of Directors of such surviving entity immediately following such transaction or (ii) the individuals or entities that beneficially owned, directly or indirectly, the shares of Voting Stock of Poseida immediately prior to such transaction cease to beneficially own, directly or indirectly, shares of Voting Stock of Poseida representing at least a majority of the total voting power of all outstanding classes of Voting Stock of the surviving entity; or

(c) Poseida sells or transfers to any Third Party, in one or more related transactions, properties or assets representing all or substantially all of Poseida’s assets to which this Agreement relates.

For the purpose of this Section 1.33, (x) “person” and “group” have the meanings given such terms under Section 13(d) and 14(d) of the United States Securities Exchange Act of 1934, and the term “group” includes any group acting for the purpose of acquiring, holding or disposing of securities within the meaning of Rule 13d-5(b)(1) under the said Act; (y) a “beneficial owner” shall be determined in accordance with Rule 13d-3 under the aforesaid Act; and (z) the terms “beneficially owned” and “beneficially own” shall have meanings correlative to that of “beneficial owner.” Notwithstanding the foregoing, (A) a transaction solely to change the domicile of Poseida; or (B) any merger or consolidation between Poseida and one or more Affiliates shall not constitute a Change in Control.

1.34 “**CICC**” or “**Chain of Identity and Chain of Control**” means a process for the capture of data related to who handled the collection of a donor’s cells or the resulting Cell Therapy, what actions were performed, and the location, data and time of the actions from the start of cell collection through product administration and post-treatment monitoring, including the association of a donor’s unique identifiers to their cells and the resulting Cell Therapy during the same.

1.35 “**CMO**” means a Third Party contract manufacturing organization.

1.36 [***]

[***] = **Certain Confidential Information Omitted**

[***].

1.37 “**Collaboration Candidate**” means, with respect to a Collaboration Program, either the Lead Collaboration Candidate or [***] [for such Collaboration Program](#).

1.38 “**Collaboration Improvements**” is defined in Section 3.4.1.

1.39 “**Collaboration IP**” means all Program Inventions and Patents claiming such Program Inventions, other than Product IP, Roche Technology Improvements, and Poseida Technology Improvements.

1.40 “**Collaboration Product**” means, with respect to a Collaboration Program, [***].

1.41 “**Collaboration Program**” means each of the research and development programs conducted under this Agreement (whether solely by Roche or jointly by the Parties) with respect to an Allo CAR T-Cell Therapy Directed To a Collaboration Target(s) (which in the case of CD19 shall be Directed To both CD19 and another Collaboration Target) but not Directed To any additional Target, including the Collaboration Research Program, and if elected by Roche pursuant to Section 3.4.6(a), the Early Development Collaboration Program with respect to such Collaboration Research Program.

1.42 “**Collaboration Research Data Package**” means a set of data, results, documents, records, and reports for each scientific hypothesis or therapeutic concept being investigated by the Parties under the Initial Collaboration Research Plan or the Additional Collaboration Research Plan, as applicable, that meets the content requirements for such set of data, results, documents, records and reports as set forth in the Initial Collaboration Research Plan or the Additional Collaboration Research Plan, as applicable, [***]; provided that any such data within the Collaboration Research Data Package that relates to patients or other clinical trial participants shall be in de-identified form in accordance with Section 10.9 of this Agreement.

1.43 “**Collaboration Research Plan**” is defined in Section 3.4.4(a).

[***] = Certain Confidential Information Omitted

1.44 “**Collaboration Research Program**” is defined in Section 3.4.3.

1.45 “**Collaboration Research Program Designation**” is defined in Section 3.4.3.

1.46 “**Collaboration Research Program Designation Fee**” is defined in Section 8.4.2.

1.47 “**Collaboration Research Term**” means, with respect to a Collaboration Research Program, the period of time from the JRT’s approval of the applicable Collaboration Research Plan until the earliest of (a) [***], (b) [***], or (c) [***] from such JRT approval of the applicable Collaboration Research Plan, as may be extended pursuant to Section 3.4.5(a).

- 1.48 “**Collaboration Research Project**” is defined in Section 3.4.1.

- 1.49 “**Collaboration Target**” is defined in Section 3.4.3.

- 1.50 “**Commercial License**” is defined in Section 6.6.4(b).

- 1.51 “**Commercial License Fee**” is defined in Section 8.5.2.

- 1.52 “**Commercial License Option**” is defined in Section 6.6.4(a).

- 1.53 “**Commercial License Option Exercise**” is defined in Section 6.6.4(a).

- 1.54 “**Commercially Reasonable Efforts**” means [***].

- 1.55 “**Competing Program**” is defined in Section 7.2.2.

- 1.56 “**Competitive Product**” means, [***]

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[***].

1.57 “**Completion**” means, with regard to a Phase I DE+, the delivery of the final study report for the Phase I DE+ to Roche.

1.58 “**Compulsory Sublicense**” means a license or sublicense granted to a Third Party, through the order, decree or grant of a governmental authority having competent jurisdiction, authorizing such Third Party to make, use, sell, offer for sale, import or export a Therapeutic Product or Licensed Product in a country or countries.

1.59 “**Compulsory Sublicensee**” means a Third Party that was granted a Compulsory Sublicense.

1.60 “**Confidential Information**” is defined in Section 10.1.

1.61 “**Control**” or “**Controlled by**” means, with respect to any Patents, Know-How or other intellectual property rights, the rightful possession (whether through ownership, license, or otherwise, other than by operations of the licenses granted herein) by a Party, as of the Execution Date or during the Term, of the ability to grant the other Party a license, sublicense or other right to exploit any item or right under such Patents, Know-How or other intellectual property rights, as provided herein, without violating the terms of any agreement with any Third Party; [***].

1.62 “**Cover**” (including variations such as “**Covered**”, “**Covering**” and the like), means, with respect to a Valid Claim in a country and in reference to a particular Therapeutic Product or Licensed Product, as applicable, (whether alone or in combination with one or more other ingredients) that the use, manufacture, sale, offer for sale or import, as applicable, of such Therapeutic Product or Licensed Product in such country would, but for ownership thereof or a license granted in this Agreement thereunder, infringe such Valid Product Claim in such country [***] or if such Valid Claim is a claim in a pending application for a Patent, would infringe such claim if it were issued.

1.63 “**CPA Firm**” means an independent, certified and internationally recognized public accounting firm selected by the auditing Party and reasonably acceptable to the Party to be audited.

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- 1.64 “**Data Room**” means, with respect to an Additional Existing Program, a virtual or physical due diligence data room containing all material data and information, including relevant Patents, relevant Third Party agreements, pre-clinical, clinical, and CMC data, and regulatory correspondence, for such Additional Existing Program to the extent Controlled by Poseida and reasonable and customary for the purpose of due diligence.
- 1.65 “**Designated Licensed Target**” is defined in Section 6.6.4(c).
- 1.66 “**Diagnostics IP**” means [***].
- 1.67 “**Directed To**” means, with respect to a Target and a Cell Therapy, that a CAR or T-cell receptor of such Cell Therapy binds directly to such Target, and such binding causes or is intended to cause pharmacologically relevant activity. When required grammatically, the defined term “Directed To” may be separated and will have the same meaning set forth above; e.g., when discussing Targets To which a product is Directed.
- 1.68 “**Disclosing Party**” is defined in Section 10.1.
- 1.69 “**Disposition Transaction**” is defined in Section 8.10.
- 1.70 “**Dispute**” is defined in Section 16.1.
- 1.71 “**Divestiture**” is defined in Section 7.2.2(b).
- 1.72 “**FTC**” is defined in Section 15.1.
- 1.73 “**Donor Selection IP**” means (a) all Know-How comprising the Donor Selection Technology and (b) all Patents claiming any such Know-How, in each case (a) and (b), Controlled by Poseida or its Affiliates as of the Execution Date or at any time thereafter until the end of the Term.
- 1.74 “**Donor Selection Technology**” means [***].
- 1.75 [***].
- 1.76 “**Early Development Candidate Success Criteria**” means, with respect to an Early Development Collaboration Program, the criteria for identifying a Lead Collaboration Candidate and [***].
- 1.77 “**Early Development Collaboration Expenses**” is defined in Section 8.4.3.
- 1.78 “**Early Development Collaboration Plan**” is defined in Section 3.4.6(a).
- 1.79 “**Early Development Collaboration Program**” is defined in Section 3.4.4(b).

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1.80 “**Early Development Collaboration Term**” means, with respect to an Early Development Collaboration Program, the period of time from the JDT’s approval of the applicable Early Development Collaboration Plan until the earliest of (a) [***], (b) [***], or (c) [***] from such JDT approval of the applicable Early Development Collaboration Plan, as may be extended pursuant to Section 3.4.7(a).

1.81 [***].

1.82 “**ED-Go Candidate Success Criteria**” means, for a Collaboration Research Program, the criteria for identifying a Lead Collaboration Candidate [***] that are suitable for [***], as set forth in the applicable Collaboration Research Plan and consistent with the general criteria in Exhibit 1.82.

1.83 “**ED-Go Data Package**” means, with respect to a Tier 2 Program or Collaboration Program, the complete set of data, results, documents, records, and reports listed in Exhibit 1.83 (as may be amended by the JRT) to enable evaluation of a Lead Collaboration Candidate and, if applicable, [***] against the relevant ED-Go Candidate Success Criteria, provided that any such data within the ED-Go Data Package that relates to patients or other clinical trial participants shall be in de-identified form in accordance with Section 10.9 of this Agreement.

1.84 “**ED-Go Decision**” is defined in Section 3.4.4(b).

1.85 “**Effective Date**” means the first (1st) Business Day immediately following the HSR Clearance Date. Upon the request of either Party, the Parties shall memorialize the Effective Date, as defined in the immediately preceding sentence, in a written document for their records.

1.86 “**Exchange**” means a securities exchange or other stock market on which a Party’s securities are traded.

1.87 “**Excluded Target**” means any Target (a) [***] or (b) [***], in each case of (a) and (b), at the time of receipt of Roche’s applicable Nomination of such Target.

1.88 “**Excluded Third Party In-License Agreements**” means those agreements set forth on Exhibit 1.88.

1.89 “**Existing Third Party Agreement Payments**” means the payments owed pursuant to the Third Party In-License Agreements existing as of the Execution Date as set forth on Exhibit 6.10.1.

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- 1.90 “**FDA**” means the United States Food and Drug Administration, or any successor entity thereto performing similar functions.
- 1.91 “**Field**” means any and all uses.
- 1.92 “**First Commercial Sale**” means [***].
- 1.93 “**FTC**” is defined in Section 15.1.
- 1.94 “**FTE**” means full-time equivalent employee (i.e., one (1) fully-committed or multiple partially-committed employees aggregating to one (1) full-time employee) by Poseida (or any of its Affiliates) and assigned to perform specific work, with such commitment of time and effort to constitute one (1) employee performing such work on a full-time basis, which for purposes hereof will be [***] hours per Calendar Year.
- 1.95 “**FTE Costs**” means all costs and expenses for the employee providing the applicable services, which shall be calculated at the FTE Rate [***].
- 1.96 “**FTE Rate**” means, with respect to an FTE, a rate of [***] per FTE per Calendar Year (to be pro-rated on an hourly basis) and is subject to [***].
- 1.97 “**Full Licensed Technologies Transfer**” is defined in Section 6.6.2(c).
- 1.98 “**German WHT Requirement**” is defined in Section 9.9.
- 1.99 “**Heme Malignancy**” means a hematologic cancer [***]

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[***].

1.100 “**HSR Act**” means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended from time to time.

1.101 “**HSR Clearance Date**” means the expiration or termination of (a) all applicable waiting periods and requests for information (and any extensions thereof) under the HSR Act and (b) any agreements with the FTC or the DOJ not to consummate the transactions contemplated by this Agreement; provided, however, that if Roche receives a letter from the FTC before the Effective Date stating that the FTC has not finished its HSR investigation, then Roche may, at its option, by written notice to Poseida, delay the Effective Date up to thirty (30) days from the expiration of the thirty (30)-day statutory waiting period under the HSR Act (not from the date of receipt of such FTC letter).

1.102 “**HSR Filing**” means filings by the Parties with the US Federal Trade Commission and the Antitrust Division of the US Department of Justice of a Notification and Report Form with respect to the matters set forth in this Agreement, together with all required documentary attachments thereto.

1.103 “**IND**” means an investigational new drug application filed with the FDA pursuant to 21 C.F.R. §312 before the commencement of clinical trials of a product, or any comparable filing with any relevant Regulatory Authority in any other jurisdiction.

1.104 “**Indemnitee**” is defined in Section 14.3.

1.105 “**Indemnitor**” is defined in Section 14.3.

1.106 “**Indication**” means a specific disease, disorder or condition that is recognized by the applicable Regulatory Authority in a given country or jurisdiction as a disease, disorder or condition. All variants of a single disease, disorder or condition (whether classified by severity or otherwise), regardless of the patient population, shall be treated as the same Indication. By way of example, (a) the treatment of a disease, disorder or condition in a particular patient population and the treatment of the same disease, disorder or condition in another population (e.g., adult population and pediatric population) shall be treated as the same Indication and (b) label expansions for a given Indication (e.g., front-line, second line, third line, metastatic, adjuvant, etc.) shall be treated as the same Indication.

1.107 “**Indirect Tax**” is defined in Section 9.10.

1.108 “**Information Security Incident**” means, with respect to Confidential Information, any unauthorized use, unauthorized disclosure, corruption (including ransomware attack) or loss or other misuse of, or unauthorized access to, such Confidential Information. Information Security Incidents do not include unsuccessful attempts or activities that do not compromise the security of Confidential Information, including unsuccessful log-in attempts, pings, port scans, denial of service attacks, or other network attacks on firewalls or networked systems.

1.109 “**Infringement**” is defined in Section 12.10.1.

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- 1.110 “**Initial Collaboration Research Plan**” is defined in Section 3.4.1
- 1.111 “**Initial Collaboration Research Program**” is defined in Section 3.4.1.
- 1.112 “**Initial Collaboration Research Term**” is defined in Section 3.4.1.
- 1.113 “**Initial Licensed Technologies Transfer**” is defined in Section 6.6.1(b).
- 1.114 “**Initial Research License Term**” is defined in Section 6.6.1(a)
- 1.115 “**Initiation**” means, with respect to a clinical trial, the first dosing of the first human subject in such clinical trial.
- 1.116 “**iPSC-Derived Licensed Product**” means [***], in either case, (a) [***], and (b) [***].
- 1.117 “**JDT**” is defined in Section 2.2.1.
- 1.118 “**JDT Co-Chair**” is defined in Section 2.2.1.
- 1.119 “**JMT**” is defined in Section 2.3.1.
- 1.120 “**JMT Co-Chair**” is defined in Section 2.3.1.
- 1.121 “**Joint IP**” is defined in Section 12.2.
- 1.122 “**Joint Patent**” means a Patent within the Joint IP.
- 1.123 “**JRT**” is defined in Section 2.1.1.
- 1.124 “**JRT Co-Chair**” is defined in Section 2.1.1.
- 1.125 “**JSC**” is defined in Section 2.4.1.
- 1.126 “**JSC Co-Chair**” is defined in Section 2.4.1.
- 1.127 “**Know-How**” means all non-public information, inventions (whether or not patentable), improvements, practices, formula, trade secrets, techniques, methods, procedures, knowledge, results, data (including pharmacological, toxicological, pharmacokinetic, pre-clinical and clinical information and test data, related reports, structure-activity relationship data, statistical analysis, and analytical and quality control data), protocols, processes, models, designs, and other information regarding discovery, development, marketing, pricing, distribution, cost, sales and manufacturing. Know-How shall not include any Patents.
- 1.128 “**Launch Quarter**” is defined in Section 8.9.3.

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1.129 “**Lead Collaboration Candidate**” is defined in Section 3.4.4.

1.130 “**Licensed Product**” means an Off-The-Shelf TCR-Expressing Cell Therapy Directed To a Designated Licensed Target but not Directed To any additional Target or a Personalized TCR- Expressing Cell Therapy. For clarity, a Licensed Product shall exclude a Tier 1 Product, Tier 2 Candidate, Optioned Tier 2 Product and Collaboration Product.

1.131 “**Licensed Target**” means a solid tumor Target designated in accordance with Section 6.6.2(d).

1.132 “**Licensed Technologies**” is defined in Section 6.6.1.

1.133 “**Licensed Technologies Know-How**” is defined in Section 6.6.2(c).

1.134 “**Loss**” or “**Losses**” is defined in Section 14.1.

1.135 “**Major European Country**” means France, Germany, Italy, Spain or the United Kingdom.

1.136 “**Manufacture**” and “**Manufacturing**” means all activities related to the production, manufacture, processing, filling, finishing, packaging, labeling, shipping, and holding of any Tier 1 Product, Tier 2 Candidate, Collaboration Product, or Licensed Product or any intermediate thereof, beginning with the selection of donors and ending with delivery of the applicable Tier 1 Product, Tier 2 Candidate, Collaboration Product, or Licensed Product (as applicable) to a patient’s treating physician or treatment center, including process development, formulation, process qualification and validation, scale-up, pre-clinical, clinical and commercial manufacture and analytic development, product characterization, stability testing, quality assurance, quality control, and establishment of CICC.

1.137 “**Manufacturing Costs**” means, with respect to a Therapeutic Product Manufactured and supplied by Poseida to Roche for development or clinical use:

(a) When Poseida or its Affiliate Manufactures such Therapeutic Product directly, the sum of (i) and (ii) below:

(i) [***]

(ii) [***].

All Manufacturing Costs in subsection (a) will be determined according to and consistent with Poseida’s Accounting Standards in the manner consistently applied to all products manufactured by Poseida.

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(b) When Poseida uses a CMO to Manufacture such Therapeutic Product, [***].

1.138 “**Manufacturing Feasibility Criteria**” means (a) for Poseida’s P-BCMA-ALLO1 Tier 1 Program, the set of criteria for the Manufacturing Process for such Tier 1 Program attached hereto as Exhibit 1.138-1, and (b) for Poseida’s P-CD19/CD20-ALLO1 Tier 1 Program, the set of criteria for the Manufacturing Process for such Tier 1 Program attached hereto as Exhibit 1.138-2, in each case as such criteria may be amended by unanimous agreement of the JMT.

1.139 [***] is defined in Section 8.2.2.

1.140 “**Manufacturing Process**” means [***].

1.141 “**Manufacturing Transition Initiation Date**” means, (a) with respect to a Tier 1 Program, the date that is the earliest of (i) [***], (ii) [***] or (iii) [***]; (b) with respect to an Optioned Tier 2 Program, the Program Transition Initiation Date; and (c) with respect to a Collaboration Program, the Program Transition Initiation Date.

1.142 “**Marketing Authorization**” means with respect to a Therapeutic Product or Licensed Product, final Regulatory Approval (including pricing approval, where required) required to sell such Therapeutic Product or Licensed Product, as applicable, for an Indication in accordance with the applicable law of a given country.

1.143 “**Materials**” means any chemical or biological substances including any: (i) organic or inorganic chemical or compound; (ii) gene; (iii) vector or construct, whether plasmid, phage, virus or any other type; (iv) host organism, including bacteria and eukaryotic cells; (v) eukaryotic or prokaryotic cell line or expression system; (vi) protein, including any peptide or amino acid sequence, enzyme, antibody or protein conferring targeting properties and any fragment of a protein or peptide or enzyme; (vii) genetic material, including any genetic control element (e.g., promoters); (viii) virus; or (ix) assay or reagent.

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1.144 “**Minimum Active Dose**” means, with respect to a Phase I DE+, the lowest dose of a Therapeutic Product that a patient receives in such Phase I DE+ [***].

1.145 [***].

1.146 “**Net Sales**” means, with respect to a given Therapeutic Product or Licensed Product in a given period on or after the First Commercial Sale in a country, [***].

1.146.1 **Sale of Therapeutic Product or Licensed Product by Roche and Affiliates.**
[***].

1.146.2 **Sale of Therapeutic Product or Licensed Product by Sublicensee.** [***].

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1.146.3 **Sale of Therapeutic Product or Licensed Product by a Compulsory Sublicensee.** [***].

1.146.4 **Therapeutic Products or Licensed Product Sold in Combination.**
[***].

1.147 **“Nomination”** is defined in Section 6.6.2(d).

1.148 **“Off-The-Shelf TCR-Expressing Cell Therapy”** means [***].

1.149 **“Option”** is defined in Section 3.2.1.

1.150 **“Option Exercise Fee”** is defined in Section 8.3.1.

1.151 **“Option Exercise Period”** is defined in Section 3.2.1.

1.152 **“Option Maintenance Election”** is defined in Section 3.2.2.

1.153 **“Option Maintenance Fee”** is defined in Section 8.3.2.

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1.154 “**Optioned Tier 2 Product**” means, with respect to an Optioned Tier 2 Program, (a) a Tier 2 Candidate within such Optioned Tier 2 Program, and (b) any Allo CAR T-Cell Therapy, other than a Collaboration Product, (i) that is Directed To [***], (ii) [***] and (iii) [***].

1.155 “**Optioned Tier 2 Program**” means a Tier 2 Program for which Roche has timely exercised its Option pursuant to Section 3.2.1 or 3.2.2.

1.156 “**Out-of-Pocket Costs**” means costs and expenses paid to Third Parties (or payable to Third Parties and accrued in accordance with Accounting Standards) by either Party or its Affiliates or Sublicensees in connection with activities under this Agreement without markup, excluding FTE Costs.

1.157 “**P-BCMA-ALLO1 Tier 1 Program**” is defined in Section 1.245.

1.158 “**P-BCMA/CD19-ALLO1 Tier 2 Program**” is defined in Section 1.248.

1.159 “**P-CD19/CD20-ALLO1 Tier 1 Program**” is defined in Section 1.245.

1.160 “**P-CD70-ALLO1 Tier 2 Program**” is defined in Section 1.248.

1.161 “**Patent**” means any and all patent or patent application or any patents issuing therefrom or claiming priority thereto, worldwide, together with any extensions (including patent term extensions and supplementary protection certificates) and renewals thereof, reissues, re-examinations, substitutions, confirmation patents, registration patents, invention certificates, patents of addition, renewals, divisionals, continuations, and continuations-in-part of any of the foregoing.

1.162 “**Personal Data**” is defined in Section 10.9.

1.163 “**Personalized TCR-Expressing Cell Therapy**” means [***].

1.164 “**Phase I Clinical Trial**” means a human clinical trial, the principal purpose of which is preliminary determination of safety and pharmacokinetics of a Therapeutic Product as described in 21 C.F.R. §312.21, or similar clinical study in a country other than the US.

1.165 “**Phase I DE+**” means the portion of a Phase I Clinical Trial in which (a) increasing doses of a Therapeutic Product are administered for the purpose of identifying a recommended dose for a Phase II Clinical Trial of such Therapeutic Product and (b) a minimum of [***]

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[***] are dosed with such Therapeutic Product at the Minimum Active Dose or higher dose as set forth in the applicable protocol.

1.166 **“Phase I DE+ Data Package”** means, with respect to a Tier 1 Program, a Tier 2 Program for which Roche has made an Option Maintenance Election, or an Early Development Collaboration Program, the complete set of data, results, documents, records, and reports (to be drafted and as may be amended by the JDT), [***] is dosed with the Minimum Active Dose or higher dose in the applicable Phase I DE+, provided that any such data within the Phase I DE+ Data Package that relates to patients or other clinical trial participants shall be in de-identified form in accordance with Section 10.9 of this Agreement. The Phase I DE+ Data Package list for the P- BCMA-ALLO1 Tier 1 Program is attached hereto as Exhibit 1.166-1. The Phase I DE+ Data Package list for the P-CD19/CD20-ALLO1 Tier 1 Program is attached hereto as Exhibit 1.166-2.

1.167 **“Phase II Clinical Trial”** means a human clinical trial, for which the primary endpoints include a determination of dose ranges or a preliminary determination of efficacy of a product in patients being studied as described in 21 C.F.R. §312.21, or similar clinical study in a country other than the US. For the avoidance of doubt, any Phase I DE+ activities within a Tier 1 Program, Tier 2 Program, or Collaboration Program shall not be considered a Phase II Clinical Trial.

1.168 **“Phase III Clinical Trial”** means a controlled human clinical trial, the principal purpose of which is to demonstrate clinically and statistically the efficacy and safety of a product for one or more Indications in order to obtain Marketing Authorization of such product for such Indication(s), as further defined in 21 C.F.R. §312.21 or a similar clinical study in a country other than the US.

1.169 **“Poseida Background IP”** means all (a) Know-How Controlled by Poseida or its Affiliates at the Execution Date or during the Term and (b) Patents claiming such Know-How. [***].

1.170 **“Poseida Indemnitees”** is defined in Section 14.2.

1.171 **“Poseida Prosecuted Patents”** is defined in Section 12.4.1.

1.172 **“Poseida Technology Improvement”** means [***]

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[***].

1.173 **“Poseida Technology Product”** means [***].

1.174 [***].

1.175 **“Prior NDA”** is defined in Section 10.6.

1.176 **“Process Development IP”** means (a) any Know-How (including any composition of matter, article of manufacture, method of use, or other subject matter), whether patentable or not, that is discovered or conceived by or on behalf of one or both Parties or their Affiliates solely or jointly with others, in the course of conducting activities pursuant to each Tier 1 Process Development Plan during the applicable Tier 1 Process Development Term, [***] and (b) any Patents claiming such Know-How.

1.177 **“Product IP”** means, with respect to a particular Therapeutic Product, a Program Invention (a) [***] or (b) [***], and (c) any Patent specifically claiming any of the foregoing in (a) or (b) and does not claim any other subject matter within Poseida Background IP.

1.178 **“Product Trademarks”** means the Trademarks to be used for the commercialization of Therapeutic Products or Licensed Products worldwide and any registrations thereof or any pending applications relating thereto worldwide (excluding, in any event, any Trademarks, service marks, names or logos that include any corporate name or logo of either Party or its Affiliate or Sublicensee).

1.179 **“Product-Specific Patent”** means [***].

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1.180 “**Program Invention**” means any Know-How (including any composition of matter, article of manufacture, method of use, or other subject matter), whether patentable or not, that is discovered or conceived by or on behalf of one or both Parties or their Affiliates solely or jointly with others, [***].

1.181 “**Program Transition**” is defined in Section 4.1.

1.182 “**Program Transition Initiation Date**” is defined (a) with respect to a Tier 1 Program, in Section 3.1.2, (b) with respect to a Tier 2 Program, in Section 3.2.1 or 3.2.3, as applicable, and (c) with respect to a Collaboration Program, in Section 3.4.4(b), 3.4.5(c), 3.4.6(b) or 3.4.7(c), as applicable.

1.183 “**Proposed Target**” is defined in Section 6.6.2(d).

1.184 “**Prosecution and Maintenance**” or “**Prosecute and Maintain**,” with respect to a given Patent, means all activities associated with the preparation, filing, prosecution, and maintenance of such Patent, as well as supplemental examinations, re-examinations, reissues, applications for patent term extensions, calculation and applications for patent term adjustments, supplementary protection certificates, and the like with respect to such Patent. For clarity, Prosecute and Maintain shall not include any such actions with respect to a Patent brought by a Third Party, including any reexaminations, inter partes reviews, and post grant reviews, as well as interferences and derivation proceedings, oppositions and other similar proceedings brought by a Third Party with respect to such Patent.

1.185 “**R&D License**” is defined in Section 6.6.2(b).

1.186 “**R&D License Fee**” is defined in Section 8.5.1.

1.187 “**R&D License Option**” is defined in Section 6.6.2(a).

1.188 “**R&D License Term**” is defined in Section 6.6.2(b).

1.189 “**Receiving Party**” is defined in Section 10.1.

1.190 “**Register**” is defined in Section 12.5.

1.191 “**Regulatory Approval**” means, with respect to a Therapeutic Product or Licensed Product, as applicable, in a country or jurisdiction, any and all approvals (including INDs and Biologics License Applications and any supplements thereto), licenses, registrations, or authorizations of any Regulatory Authority necessary to Manufacture, use, store, import, transport, commercially distribute, sell, or market such Therapeutic Product or Licensed Product, as applicable in such country, including, where applicable, (a) pricing or reimbursement approval in

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such country, (b) post-approval marketing authorizations (including any prerequisite Manufacturing approval or authorization related thereto), and (c) labeling approval.

1.192 **“Regulatory Authority”** means any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity with authority over the development, Manufacturing, commercialization or other use or exploitation (including the granting of Regulatory Approvals) of the pharmaceutical or biological products in any jurisdiction, including the FDA.

1.193 **“Regulatory Documentation”** means all (a) applications (including all INDs and other regulatory filings), registrations, licenses, authorizations, and approvals (including Regulatory Approvals); (b) correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents with respect thereto, including all regulatory drug lists, adverse event files, and complaint files; and (c) data, including all information that is made, collected, or otherwise generated pursuant to a clinical trial, contained or relied upon in any of the foregoing (including data related to the Manufacturing Process), in each case ((a), (b), and (c)) relating to a Therapeutic Product.

1.194 **“Regulatory Transfer”** is defined in Section 4.1.1.

1.195 **“Release”** is defined in Section 11.2.

1.196 [***].

1.197 [***].

1.198 [***].

1.199 [***].

1.200 [***].

1.201 **“Roche Background IP”** means all (a) Know-How Controlled by Roche or its Affiliates at the Execution Date or during the Term and (b) Patents claiming such Know-How, in each case (a) and (b). [***].

1.202 **“Roche Indemnities”** is defined in Section 14.1.

1.203 **“Roche Materials”** is defined in Section 3.5.1.

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- 1.204 “**Roche Product**” means any proprietary therapeutic product developed, in-licensed or acquired by Roche that is not the subject of this Agreement.
- 1.205 “**Roche Prosecuted Patents**” is defined in Section 12.4.2(a).
- 1.206 “**Roche Technology Improvement**” means [***].
- 1.207 [***].
- 1.208 [***].
- 1.209 [***].
- 1.210 [***].
- 1.211 [***].
- 1.212 “**Royalty Eligible Allogeneic Licensed Product**” is defined in Section 8.8.3(a).
- 1.213 “**Royalty Eligible Autologous Licensed Product**” is defined in Section 8.8.3(a).
- 1.214 “**Royalty Term**” is defined in Section 8.8.4.
- 1.215 “**Rules**” is defined in Section 16.2.1.
- 1.216 “**Sales**” means [***]

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[***].

1.217 “**Sell-Off Period**” is defined in Section 15.7.4.

1.218 “**Study Plan**” is defined in Section 6.6.1(a).

1.219 “**Sublicensee**” means any Third Party, other than [***], to which Roche or any of its Affiliates grants a sublicense under the rights licensed to Roche under this Agreement to commercialize a Therapeutic Product or Licensed Product.

1.220 “**Target**” means a naturally occurring human protein or biological molecule from which an antigen is derived, including all peptides derived from such protein and all forms (including forms arising from mutations in the gene that encodes such protein or biological molecule) of such protein or biological molecule.

1.221 “**Target Extension Fee**” is defined in Section 8.5.3.

1.222 “**Technical Update**” is defined in Section 6.7.

1.223 “**Technology Transfer**” is defined in Section 5.4.

1.224 “**Technology Transfer Plan**” means, with respect to the Technology Transfer of a Therapeutic Program, the plan that (a) lists documents and Materials (i) to be transferred from Poseida to Roche during the Technology Transfer to effect the Technology Transfer and (ii) [***],

(b) describes activities to be undertaken by the Parties to facilitate the transfer of such Know-How and (c) states an estimated timeline and allocation of responsibility with respect to such Technology Transfer, in each case (a)-(c), to denote successful completion of the Technology Transfer consistent with the general criteria set forth in Exhibit 1.224.

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1.225 [***].

1.226 [***].

1.227 [***].

1.228 [***].

1.229 [***].

1.230 “**Term**” is defined in Section 15.2.

1.231 [***].

1.232 “**Therapeutic Product**” means a Tier 1 Product, an Optioned Tier 2 Product, or a Collaboration Product.

1.233 “**Therapeutic Program**” means a Tier 1 Program, Optioned Tier 2 Program, or a Collaboration Program.

1.234 “**Third Party**” means any entity other than a Party or any of its Affiliates.

1.235 “**Third Party Claims**” is defined in Section 14.1.

1.236 “**Third Party In-License Agreements**” means any contract or agreement with a Third Party pursuant to which Poseida, during the Term, in-licenses or otherwise maintains Control of Patents, Know-How or other intellectual property rights for purposes of this Agreement (which, for clarity, subject to Section 6.10.3, exclude the Excluded Third Party In-License Agreements).

1.237 “**Tier 1 Activities**” is defined in Section 3.1.2.

1.238 “**Tier 1 Development Expenses**” is defined in Section 8.2.1.

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1.239 “**Tier 1 Development Plan**” is defined in Section 3.1.2.

1.240 “**Tier 1 Development Term**” means, with respect to a Tier 1 Development Program, the period of time from the Effective Date until the Completion of the Phase I DE+ for the applicable Tier 1 Program.

1.241 “**Tier 1 Process Development Plan**” is defined in Section 5.1.

1.242 “**Tier 1 Process Development Program**” is defined in Section 5.1.

1.243 “**Tier 1 Process Development Term**” means, with respect to a Tier 1 Process Development Program, the period of time from the JMT’s approval of the applicable Tier 1 Process Development Plan until Technology Transfer of the applicable Tier 1 Program.

1.244 “**Tier 1 Product**” means, (a) with respect to the P-BCMA-ALLO1 Tier 1 Program, Poseida’s Allo CAR T-Cell Therapy product known as P-BCMA-ALLO1, (b) with respect to the P-CD19/CD20-ALLO1 Tier 1 Program, Poseida’s Allo CAR T-Cell Therapy product known as P-CD19/CD20-ALLO1, or (c) [***].

1.245 “**Tier 1 Program**” means each of (a) Poseida’s program for the research and development of Allo CAR T-Cell Therapies Directed To BCMA alone (the “**P-BCMA-ALLO1 Tier 1 Program**”), and (b) Poseida’s program for the research and development of Allo CAR T-Cell Therapies Directed To both CD19 and CD20 (the “**P-CD19/CD20-ALLO1 Tier 1 Program**”).

1.246 “**Tier 1 Target**” means (a) with respect to the P-BCMA-ALLO1 Tier 1 Program, B-cell maturation antigen (“BCMA”) (also known as tumor necrosis factor receptor superfamily member 17 (TNFRSF17)) and (b) with respect to the P-CD19/CD20-ALLO1 Tier 1 Program, each of CD19 and CD20.

1.247 “**Tier 2 Candidate**” means, (a) with respect to the P-BCMA/CD19-ALLO1 Tier 2 Program, Poseida’s Allo CAR T-Cell Therapy product known as P-BCMA/CD19-ALLO1 and (b) with respect to the P-CD70-ALLO1 Tier 2 Program, Poseida’s Allo CAR T-Cell Therapy candidate(s) to be designated by Poseida as it progresses such program.

1.248 “**Tier 2 Program**” means each of (a) Poseida’s program for the research and development of Allo CAR T-Cell Therapies Directed To both BCMA and CD19 (the “**P-BCMA/CD19-ALLO1 Tier 2 Program**”), and (b) Poseida’s program for the research and development of Allo CAR T- Cell Therapies Directed To CD70 alone (the “**P-CD70-ALLO1 Tier 2 Program**”).

1.249 “**Tier 2 Target**” means (a) with respect to the BCMA/CD19-ALLO1 Tier 2 Program, each of BCMA and CD19 and (b) with respect to the P-CD70-ALLO1 Tier 2 Program, CD70 (also known as tumor necrosis factor superfamily member 7 (TNFSF7)).

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1.250 “**Title 11**” is defined in Section 15.4.

1.251 “**Trademark**” means any word, name, symbol, color, designation or device or any combination thereof that functions as a source identifier, including any trademark, trade dress, brand mark, service mark, trade name, brand name, logo or business symbol, whether or not registered.

1.252 [***].

1.253 “**Tscm-Enabling IP**” means (a) all Know-How comprising Tscm-Enabling Technology and (b) all Patents claiming any such Know-How or otherwise Covering any Tscm-Enabling Technology, in each case (a) and (b), Controlled by Poseida or its Affiliates as of the Execution Date or at any time thereafter until the end of the Term. The Patents in clause (b) existing as of the Execution Date are listed on Exhibit 1.253.

1.254 “**Tscm-Enabling Technology**” means [***].

1.255 “**US**” means the United States of America and its territories and possessions.

1.256 “**US Dollars**” or “**\$**” means US dollars.

1.257 “**Valid Claim**” means (a) with respect to a Therapeutic Product or Licensed Product, a claim of an issued and unexpired Patent that has not been (i) disclaimed; (ii) dedicated to the public; (iii) abandoned; (iv) declared invalid, unenforceable or revoked by a decision of a court, government agency or other authority having jurisdiction, which decision is unappealable or unappealed within the time allowed for appeal; or (v) admitted to be invalid or unenforceable through reexamination, reissue or otherwise, or (b) with respect to a Therapeutic Product, a claim of a pending application for a Patent that (i) was filed in good faith and with a reasonable belief that such claim will be found patentable and granted, (ii) has been pending for less than [***] and (iv) has not been finally cancelled, withdrawn, abandoned or rejected by an administration agency action from which no appeal can be taken.

1.258 “**Valid Product Claim**” means, (a) for a Tier 1 Product or Optioned Tier 2 Product, a Valid Claim in a [***], (b) for a Collaboration Product, a Valid Claim [***], (c) for a Royalty-Eligible Autologous Licensed Product or a Royalty-Eligible Allogeneic Licensed Product, a Valid Claim in a Patent [***],

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and (d) for an iPSC-Derived Licensed Product, a Valid Claim in a Patent [***].

1.259 “**Voting Stock**” is defined in Section 1.33(a).

1.260 “**Withholding Tax Action**” is defined in Section 9.8.

1.261 “**Working Group**” is defined in Section 2.5.

ARTICLE 2 Governance

2.1 Joint Research Team.

2.1.1 **Formation and Composition.** Promptly after the Effective Date, and in any event within [***], after the Effective Date, the Parties shall establish a joint research team (the “**JRT**”) to coordinate and provide oversight with respect to activities under the Initial Collaboration Research Program, Additional Collaboration Research Program (as applicable), and Collaboration Research Programs prior to the JRT’s confirmation of a Lead Collaboration Candidate or Back-Up Collaboration Candidate(s) that meets the applicable ED-Go Candidate Success Criteria and to receive status updates on Tier 2 Programs until Poseida’s selection of a Tier 2 Candidate for which to commence IND-enabling activities. The JRT shall be composed of up to [***] representatives designated by each of Poseida and Roche (though the Parties need not have the same number of representatives on the JRT). Each Party shall designate one of its representatives as its primary contact for JRT matters (such Party’s “**JRT Co-Chair**”). The Parties, through their respective Alliance Managers, shall align on membership of the JRT ensuring that representatives are appropriate for the tasks then being undertaken and the stage of research, in terms of their seniority, function in their respective organizations, training and experience. A Party may replace any or all of its JRT representatives (or JRT Co-Chair) at any time by informing the other Party in advance in writing (which may be by email). Once established, the JRT shall meet [***]. Either Party may invite a reasonable number of other employees, consultants, research contractors, or scientific advisors to attend a JRT meeting in a non-voting capacity with prior written notice to the other Party; provided that such invitees are bound by appropriate confidentiality and invention assignment obligations consistent with the terms of this Agreement. Unless otherwise agreed by the Parties, the JRT shall meet and operate during the period commencing upon its formation until [***] after the last to occur of (a) expiration of the last Collaboration Research Term or (b) completion of all activities under all Tier 2 Programs prior to Poseida’s selection of the applicable Tier 2 Candidate to commence IND-enabling activities therefor. Thereafter, the JRT shall cease operations and perform no further functions under this Agreement. Notwithstanding the foregoing, following dissolution of the JRT, the Parties upon mutual agreement may re-establish the JRT as needed.

2.1.2 **Responsibilities of the JRT.** The JRT shall be responsible for performing the following functions:

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- (a) consulting with the JDT as needed regarding any activities before the JRT's confirmation of a Lead Collaboration Candidate or [***] that meets the applicable ED-Go Candidate Success Criteria for each Tier 1 Program;
- (b) monitoring and discussing the progress of each Tier 2 Program prior to Poseida's selection of a Tier 2 Candidate to commence IND-enabling activities therefor;
- (c) reviewing and discussing the ED-Go Data Packages prepared by Poseida for each Tier 2 Program as set forth in Section 3.2.1 (provided that for the avoidance of doubt, Roche and not the JRT shall have the sole right to make an Option Maintenance Election pursuant to Section 3.2.2 or to exercise an Option pursuant to Section 3.2.1 or 3.2.3);
- (d) monitoring and discussing the progress of the Initial Collaboration Research Program and, if applicable, the Additional Collaboration Research Program;
- (e) drafting and approving any amendments to the Initial Collaboration Research Plan (including alternative Collaboration Research Projects) and, if applicable, drafting and approving the Additional Collaboration Research Plan, and any amendments thereto (including alternative Additional Collaboration Research Projects) (provided that for the avoidance of doubt, Roche and not the JRT shall have the sole right to select the Collaboration Research Projects to be tested);
- (f) reviewing and discussing the Collaboration Research Data Packages prepared by the Parties for each Collaboration Research Project as set forth in Sections 3.4.1 and 3.4.2 (provided that for the avoidance of doubt, Roche and not the JRT shall have the sole right to make a Collaboration Research Program Designation pursuant to Section 3.4.3);
- (g) drafting and approving the Collaboration Research Plans (including the applicable ED-Go Candidate Success Criteria under Section 3.4.4), and any amendments thereto;
- (h) identifying a Lead Collaboration Candidate and one or two Back-Up Collaboration Candidate(s) for each Collaboration Research Program;
- (i) reviewing and discussing test results for potential Lead Collaboration Candidates and [***] against the applicable ED-Go Candidate Success Criteria and determining whether or not such ED-Go Candidate Success Criteria have been met;
- (j) reviewing and approving any ED-Go Candidate Remediation Plan for a Collaboration Research Program;
- (k) coordinating Program Transition for Optioned Tier 2 Programs for which Roche does not make an Option Maintenance Election pursuant to Section 3.2.2 and for Collaboration Research Programs for which Roche makes an ED-Go Decision and does not elect an Early Development Collaboration Program under Section 3.4.4(b), as applicable;
- (l) establishing, dissolving and overseeing Working Groups, as appropriate, to carry out its functions and resolving any Disputes that arise in such Working Groups; and

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(m) performing such other functions as agreed to by the Parties or as specified in this Agreement.

2.1.3 **Decisions.** The JRT shall operate as to matters within its responsibility by attempting to reach agreement by consensus, with each Party casting [***]. In the event that agreement on a particular matter cannot be reached by the JRT within [***] or such longer period as the JRT members agree, after the JRT first meets to consider such matter, the matter shall be referred to the JSC, which shall resolve such matter in accordance with Section 2.4.3.

2.2 **Joint Development Team.**

2.2.1 **Formation and Composition.** Within [***] after the Effective Date, the Parties shall establish a joint development team (the “**JDT**”) to coordinate and provide oversight with respect to the Tier 1 Activities, activities under any Early Development Collaboration Programs, and development activities conducted by Poseida for any Tier 2 Program for which Roche makes an Option Maintenance Election pursuant to Section 3.2.2 (but only until the earlier of Roche’s timely exercise of its Option for such Tier 2 Program or the expiration of the Option Exercise Period for such Tier 2 Program without exercise by Roche of the Option). The JDT shall be composed of up to [***] representatives designated by each of Poseida and Roche (though the Parties need not have the same number of representatives on the JDT). Each Party shall designate one of its representatives as its primary contact for JDT matters (such Party’s “**JDT Co-Chair**”). The Parties, through their respective Alliance Managers, shall align on membership of the JDT ensuring that representatives are appropriate for the tasks then being undertaken and the stage of development, in terms of their seniority, function in their respective organizations, training and experience. A Party may replace any or all of its JDT representatives (or JDT Co-Chair) at any time by informing the other Party in advance in writing (which may be by email). Once established, the JDT shall meet [***]. Either Party may also invite a reasonable number of other employees, consultants, clinical contractors, or scientific advisors to attend a JDT meeting in a non-voting capacity with prior written notice to the other Party; provided that such invitees are bound by appropriate confidentiality and invention assignment obligations consistent with the terms of this Agreement. Unless otherwise agreed by the Parties, the JDT shall meet and operate during the period commencing upon its formation until completion of the last Program Transition of a Tier 1 Program, Optioned Tier 2 Program, or Collaboration Research Program (or Early Development Collaboration Program, as applicable), unless earlier dissolved by the JSC. Thereafter, the JDT shall cease operations and perform no further functions under this Agreement.

2.2.2 **Responsibilities of the JDT.** The JDT shall be responsible for performing the following functions:

(a) monitoring and discussing the progress (including budgets) of the Tier 1 Programs until Program Transition and of any Tier 2 Program for which Roche makes an Option Maintenance Election pursuant to Section 3.2.2 (including interactions with Regulatory Authorities concerning such Tier 2 Program) until the earlier of Program Transition or expiration of the applicable Option Exercise Period without Roche exercising its Option;

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- (b) drafting and approving the Tier 1 Development Plan for the P-CD19/CD20-ALLO1 Tier 1 Program;
- (c) drafting and approving any amendments to the Tier 1 Development Plan (including any protocol amendments) for each Tier 1 Program;
- (d) reviewing and discussing the Phase I DE+ data for each Tier 1 Program on a quarterly basis and the final Phase I DE+ Data Packages;
- (e) reviewing and discussing the Phase I DE+ data for each Tier 2 Program for which Roche has made an Option Maintenance Election as set forth in Section 3.2.2 and final Phase I DE+ Data Package (provided that for the avoidance of doubt, Roche and not the JRT shall have the sole right to exercise the Option pursuant to Section 3.2.3);
- (f) drafting and approving the Early Development Collaboration Plan (including the Early Development Candidate Success Criteria) for an Early Development Collaboration Program as set forth in Section 3.4.6, and any amendments thereto;
- (g) reviewing and discussing data and results for potential Lead Collaboration Candidates and [***] [against the applicable Early Development Candidate Success Criteria](#);
- (h) reviewing and approving any Early Development Candidate Remediation Plan for an Early Development Collaboration Program;
- (i) coordinating the preparation of, and involvement in, interactions with Regulatory Authorities in the development of Therapeutic Programs, prior to and during Regulatory Transfer (and at Roche's request after Regulatory Transfer), including discussing the implementation of any action plan to address requests from a Regulatory Authority with respect to such Therapeutic Programs;
- (j) coordinating with the JMT to consider manufacturing and CMC in the development of each Therapeutic Program;
- (k) coordinating Program Transition for Tier 1 Programs, Optioned Tier 2 Programs for which Roche made an Option Maintenance Election pursuant to Section 3.2.2, and Early Development Collaboration Programs, as applicable;
- (l) establishing, dissolving and overseeing Working Groups, as appropriate, to carry out its functions and resolving any Disputes that arise in such Working Groups; and
- (m) performing such other functions as agreed to by the Parties or as specified in this Agreement.

2.2.3 **Decisions.** The JDT shall operate as to matters within its responsibility by attempting to reach agreement by consensus, with each Party casting [***]. In the event that agreement on a particular matter cannot be reached by the JDT within [***] or such longer period as the JDT members agree, after the JDT first meets to consider such

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matter, the matter shall be referred to the JSC, which shall resolve such matter in accordance with Section 2.4.3.

2.3 Joint Manufacturing Team.

2.3.1 **Formation and Composition.** Within [***] of the Effective Date, the Parties shall establish a joint manufacturing team (the “**JMT**”) to coordinate and oversee: (a) the Technology Transfer for each Tier 1 Program, Optioned Tier 2 Program and Collaboration Program and (b) prior to the applicable Technology Transfer, the development, improvement, validation and performance of the Manufacturing Process for each Tier 1 Program, Tier 2 Program, and Collaboration Program. The JMT shall be composed of up to [***] representatives designated by each of Poseida and Roche (though the Parties need not have the same number of representatives on the JMT). Each Party shall designate one of its representatives as its primary contact for JMT matters (such Party’s “**JMT Co-Chair**”). The Parties, through their respective Alliance Managers, shall align on membership of the JMT ensuring that representatives are appropriate for the tasks then being undertaken and the stage of Manufacturing Process development, in terms of their seniority, availability, function in their respective organizations, training and experience. A Party may replace any or all of its JMT representatives (or JMT Co-Chair) at any time by informing the other Party in advance in writing (which may be by email). Once established, the JMT shall meet [***]. Either Party may invite a reasonable number of other employees, consultants, manufacturing contractors, or scientific advisors to attend a JMT meeting in a non-voting capacity with prior written notice to the other Party; provided that such invitees are bound by appropriate confidentiality and invention assignment obligations consistent with the terms of this Agreement. The JMT shall meet and operate during the period commencing upon its formation until completion of the last Technology Transfer of a Tier 1 Program, Optioned Tier 2 Program, or Collaboration Program, unless earlier dissolved by the JSC. Thereafter, the JMT shall cease operations and perform no further functions under this Agreement.

2.3.2 **Responsibilities of the JMT.** The JMT shall be responsible for performing the following functions:

- (a) drafting and approving the Tier 1 Process Development Plan for each Tier 1 Program, and any amendments thereto;
- (b) drafting and approving the Technology Transfer Plans, and any amendments thereto;
- (c) reviewing and discussing, no less than once per Calendar Quarter, the Manufacturing Costs for a Tier 1 Program;
- (d) [***];
- (e) reviewing and determining whether or not Poseida has achieved the applicable Manufacturing Feasibility Criteria for a Tier 1 Program;
- (f) coordinating the initial technology transfers for each Tier 1 Program pursuant to Section 5.3;

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- (g) coordinating the Technology Transfer for each Tier 1 Program, Optioned Tier 2 Program, and Collaboration Program;
- (h) prior to the applicable Technology Transfer, discussing Manufacturing Process development and improvement updates and coordinating and proposing to the JRT or JDT, as applicable, any of such Manufacturing Process improvements, for each Tier 1 Program, Tier 2 Program, or Collaboration Program;
- (i) coordinating with the JDT to provide CMC and manufacturing updates as they pertain to the development of each Therapeutic Program;
- (j) coordinating with the JDT to create and implement any action plans to address requests from a Regulatory Authority with respect to each Therapeutic Program;
- (k) coordinating the Initial Licensed Technologies Transfer pursuant to Section 6.6.1(b) and Full Licensed Technologies Transfer pursuant Section 6.6.2(c) and any updates thereto;
- (l) discussing and attempting to resolve any potential or evolving disagreement between the Parties related to the Manufacturing Process development or Technology Transfers;
- (m) establishing CICC and data integrity procedures and policies;
- (n) establishing, dissolving and overseeing Working Groups, as appropriate, to carry out its functions and resolving any Disputes that arise in such Working Groups; and
- (o) performing such other functions as agreed to by the Parties or as specified in this Agreement.

2.3.3 **Decisions.** The JMT shall operate as to matters within its responsibility by attempting to reach agreement by consensus, with each Party casting [***]. In the event that agreement on a particular matter cannot be reached by the JMT within [***] or such longer period as the JMT members agree, after the JMT first meets to consider such matter, the matter shall be referred to the JSC, which shall resolve such matter in accordance with Section 2.4.3.

2.4 Joint Steering Committee.

2.4.1 **Formation and Composition.** Within [***] of the Effective Date, the Parties shall establish a joint steering committee (the “JSC”) to monitor and provide strategic oversight of the activities under this Agreement, all in accordance with this Section 2.4.1. The JSC shall be composed of up to [***] representatives from each of the Parties (though the Parties need not have the same number of representatives on the JSC). Each Party shall designate one of its representatives as its primary contact for JSC matters (such Party’s “JSC Co-Chair”). The Parties, through their respective Alliance Managers, shall align on membership of the JSC ensuring that representatives are appropriate for the issues germane to the Dispute in terms of their seniority, availability, function in their respective organizations, training and experience. A Party may replace any or all of its JSC representatives (or JSC Co-Chair) at any time by informing the

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other Party in advance in writing (which may be by email). Once established, the JSC shall meet [***] and shall meet at such other times as deemed appropriate by the JSC. Either Party may invite a reasonable number of other employees, consultants, contractors or scientific advisors to attend a JSC meeting with prior written notice to the other Party; provided that such invitees are bound by appropriate confidentiality and invention assignment obligations consistent with the terms of this Agreement. The JSC shall meet and operate during the period commencing upon its formation until each of the JRT, JDT and JMT have been dissolved, unless earlier dissolved by mutual agreement by the Parties. Thereafter, the JSC shall cease operations and perform no further functions under this Agreement.

2.4.2 **Responsibilities of the JSC.** The JSC shall be responsible for performing the following functions:

- (a) reviewing and discussing the research, development, and Manufacture of Therapeutic Products and any other ongoing activities under this Agreement;
- (b) facilitating the flow of information between the Parties with respect to the research, development, and Manufacture of Therapeutic Products;
- (c) overseeing the activities of the JRT, JDT, and JMT and providing guidance thereto;
- (d) attempting to resolve issues presented to it by, and Disputes within, each of the JRT, JDT, JMT and the JSC's Working Groups;
- (e) establishing, dissolving, and overseeing any JSC Working Groups as appropriate, to carry out its functions and resolving any Disputes that arise in such Working Groups;
- (f) dissolving or re-establishing each of the JRT, JDT, and JMT; and
- (g) performing such other functions as agreed to by the Parties or as specified in this Agreement.

2.4.3 **Decisions.** The JSC shall operate as to matters within its responsibility by attempting to reach agreement by consensus, with each Party casting [***]. If the JSC cannot, or does not, reach consensus on an issue at a meeting or within [***] thereafter, then (a) [***] and (b) [***]; provided that:

- (i) neither Party shall have the right to amend the Agreement or waive its obligations under the Agreement;

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(iii) [***].

[***]; and

(ii) neither Party shall have the final decision-making authority over:

2.5 **Working Groups.** From time to time, the JRT, JDT, JMT, or JSC may establish and delegate duties to sub-committees or directed teams (each, a “**Working Group**”) on an as-needed basis to oversee particular projects or activities. Each such Working Group shall be constituted and shall operate as the applicable JRT, JDT, JMT, or JSC determines; provided that each Working Group shall have equal representation from each Party, unless otherwise mutually agreed. Working Groups may be established on an ad hoc basis for specific purposes and durations. Each Working Group and its activities shall be subject to the oversight, review and approval of, and shall report to, the committee or team that formed said Working Group. In no event shall the authority of the Working Group exceed that specified for the applicable JRT, JDT, JMT, or JSC that formed the Working Group to this Article 2. All decisions of a Working Group shall be made by consensus. Any disagreement between the designees of Roche and Poseida on a Working Group shall be referred to the applicable JRT, JDT, JMT, or JSC that formed the Working Group for resolution. In the event that the JRT, JDT, JMT, or JSC is disbanded, then the Working Groups thereunder shall also automatically be disbanded.

2.6 **Committee Meetings; Minutes.** In order to hold any committee or team meeting or to make a committee or team decision under this Article 2, at least [***] of such committee or team from each Party must participate in the meeting or vote; provided that either Party may defer a meeting or a vote if such Party desires to postpone until the applicable committee or team members are able to attend, so long as such postponement does not cause material or undue delays to any Tier 1 Program, Tier 2 Program, or Collaboration Program. Committees may meet in person or via teleconference, video conference or the like, provided that [***], unless otherwise agreed by the Parties. Each Party shall bear the expense of its respective representatives’ participation in committee and team meetings. Each committee or team shall keep minutes of its meetings that record in writing any key decisions made. Action items assigned or completed and other appropriate matters may be recorded in such meeting minutes as needed. The Parties shall alternate the responsibility for keeping such meeting minutes for a particular committee or team. Meeting minutes shall be sent to both Parties promptly after a meeting for review, comment and approval. A decision that is made at a committee or team meeting shall be recorded in minutes and decisions that are made by the committee or team outside of a meeting shall be documented in writing (which may be by email).

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2.7 **Alliance Managers.** Promptly following the Effective Date, each Party shall designate an individual to act as the primary business contact for such Party for matters related to this Agreement (such Party's "**Alliance Manager**"), unless another contact is expressly specified in the Agreement or designated by the Parties for a particular purpose. The Alliance Managers shall promote communication and collaboration between the Parties, ensure appropriate decision making, and assist in the resolution of potential and pending issues and potential Disputes in a timely manner. The Alliance Managers may attend all meetings of the committees and teams contemplated herein as non-voting participants. Either Party may replace its Alliance Manager at any time by notifying the other Party's Alliance Manager in writing (which may be by email).

2.8 **Limitations on Authority.** Each Party shall retain the rights, powers, and discretion granted to it under this Agreement, and no such rights, powers, or discretion shall be delegated to or vested in a committee or team unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing. No committee or team shall have the power to amend, modify or waive compliance with this Agreement, which may only be amended or modified, or compliance with which may only be waived, as provided in Section 17.8.

2.9 **Party Structure.** The Parties recognize that each Party possesses an internal structure (including various committees, teams and review boards) that will be involved in administering such Party's activities under this Agreement. Each Party shall have the right to make routine day- to-day decisions relating to the conduct of those activities for which it has a performance or other obligation hereunder, in each case in a manner consistent with the then-current applicable plan and the terms and conditions of this Agreement.

ARTICLE 3

Tier 1 Programs; Tier 2 Programs; Collaboration Programs

3.1 Tier 1 Programs

3.1.1 **General.** For each Tier 1 Program, except with respect to the Tier 1 Activities as described in Section 3.1.2 and the Manufacturing activities under Section 5.1, as between the Parties, Roche shall be responsible for all aspects of research and development of Tier 1 Products, which it shall conduct in its sole discretion and control, [***].

3.1.2 **Tier 1 Development Plan; Conduct of Tier 1 Activities.** For each Tier 1 Program, in addition to its Manufacturing activities as set forth in Section 5.2.1(a), Poseida shall be responsible for conducting all research and development activities through the Completion of Phase I DE+ (the "**Tier 1 Activities**") as set forth in a written development plan agreed upon by the JDT, as may be amended by the JDT (each, a "**Tier 1 Development Plan**"). The initial Tier 1 Development Plan for the P-BCMA-ALLO1 Tier 1 Program is attached hereto as Exhibit 3.1.2- 1 and the initial Tier 1 Development Plan for the P-CD19/CD20-ALLO1 Tier 1 Program is attached hereto as Exhibit 3.1.2-2. Poseida shall use Commercially Reasonable Efforts to perform the Tier 1 Activities under each Tier 1 Development Plan within the timelines and budgets set forth therein. Poseida shall provide Roche regular updates on the progress of the Tier 1 Programs at JDT meetings (with consultation by the JRT as needed for activities conducted prior to commencing IND-enabling activities, if any). [***], Poseida shall perform all such Tier 1 Activities [***] and under the JDT's oversight. For clarity, any

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activities to be performed with respect to a Phase I DE+ after Completion of such Phase I DE+ (e.g., additional patient enrollment, clinical site maintenance, study wind-down, or patient follow-up) shall be conducted by Roche [***]; provided however, in the event that Roche requests that Poseida conduct, and Poseida consents to conducting, any post-Completion of Phase I DE+ activities for such Phase I DE+, the Parties shall discuss the scope, duration, and budget of such activities, and the FTE Costs and Out-of-Pocket Costs incurred by Poseida in the performance of such activities shall be [***]. Notwithstanding the foregoing, [***]. For each Tier 1 Program, the Program Transition Initiation Date shall be deemed to have occurred on the date of the earlier of (a) the completion of all Tier 1 Activities for such Tier 1 Program or (b) the assumption by Roche of all then-remaining Tier 1 Activities pursuant to the preceding sentence for such Tier 1 Program.

3.2 **Tier 2 Programs**

3.2.1 **Exclusive Option; Option Exercise at ED-Go.** For each Tier 2 Program, Poseida hereby grants Roche an exclusive option to acquire the exclusive license set forth in Section 6.2.1 (each, an “**Option**”). Poseida shall use Commercially Reasonable Efforts to continue the research activities with respect to each Tier 2 Program, [***], until achieving Poseida has selected a Tier 2 Candidate ready to commence IND-enabling activities. Poseida shall provide Roche with prompt written notice of such Tier 2 Candidate selection for each Tier 2 Program. Promptly following such Tier 2 Candidate selection but in no event later than [***] thereafter, Poseida shall prepare, and deliver to Roche, an ED-Go Data Package for the applicable Tier 2 Program. At any time between the Effective Date and [***] after Roche’s receipt of the complete ED-Go Data Package for the applicable Tier 2 Program (as such period may be extended under Section 3.2.2) (the “**Option Exercise Period**”), Roche may exercise its Option by providing written notice to Poseida of such exercise. If Roche exercises the Option for a Tier 2 Program pursuant to this Section 3.2.1 at any time, Roche shall be deemed to have exercised the “Option at ED-Go” and shall pay the “ED-Go” Option Exercise Fee for such Tier 2 Program to Poseida pursuant to Section 8.3.1. Upon Poseida’s receipt of Roche’s written notice of its exercise of the Option for a Tier 2 Program pursuant to this Section 3.2.1, and after the HSR Clearance Date, if applicable, with respect to the exercise of such Option, such Tier 2 Program shall be deemed an Optioned Tier 2 Program, the licenses granted to Roche under Section 6.2 shall become effective with respect to such Optioned Tier 2 Program, and the Program Transition Initiation Date shall be deemed to have occurred on such date with respect to such Optioned Tier 2 Program.

3.2.2 **Option Maintenance Election.** Notwithstanding anything to the contrary in Section 3.2.1, for each Tier 2 Program, at any point prior to the expiration of the applicable Option Exercise Period, Roche may elect not to exercise its Option pursuant to Section 3.2.1, but instead elect to: (a) have Poseida use Commercially Reasonable Efforts to continue leading research and development activities for such Tier 2 Program, [***], until the Completion of the Phase I DE+, (b) promptly following such Completion of a Phase I DE+, have Poseida prepare, and deliver to Roche, a Phase I DE+ Data Package for such Tier 2 Program, and (c) extend

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the expiration date of its Option Exercise Period for such Tier 2 Program until [***] after Roche's receipt of the complete Phase I DE+ Data Package (an "**Option Maintenance Election**"). Roche may make an Option Maintenance Election by providing written notice to Poseida of such Option Maintenance Election prior to expiration of the Option Exercise Period under Section 3.2.1 for the applicable Tier 2 Program. If Roche makes such an Option Maintenance Election for a Tier 2 Program, Roche shall pay Poseida an Option Maintenance Fee for such Tier 2 Program pursuant to Section 8.3.2. Upon Poseida's receipt of Roche's written notice of its Option Maintenance Election for a Tier 2 Program, the abovementioned clauses (a)-(c) shall become effective for such Tier 2 Program.

3.2.3 **Option Exercise at Phase I DE+.** Roche may exercise its Option for a Tier 2 Program for which Roche has made an Option Maintenance Election and paid the Option Maintenance Fee at any time prior to expiration of the extended Option Exercise Period by providing written notice to Poseida of such exercise. If Roche exercises the Option for a Tier 2 Program pursuant to this Section 3.2.3 at any time, Roche shall be deemed to have exercised the Option at "Phase I DE+" and shall pay Poseida the "Phase I DE+" Option Exercise Fee pursuant to Section 8.3.1. Upon Poseida's receipt of Roche's written notice of its exercise of the Option for a Tier 2 Program pursuant to this Section 3.2.3 and the payment of the "Phase I DE+" Option Exercise Fee for such Tier 2 Program pursuant to Section 8.3.1, such Tier 2 Program shall be deemed an Optioned Tier 2 Program, the licenses granted to Roche under Section 6.2 shall become effective with respect to such Optioned Tier 2 Program, and the Program Transition Initiation Date shall be deemed to have occurred on such date with respect to such Optioned Tier 2 Program.

3.2.4 **Reporting.** During each Option Exercise Period, Poseida shall provide Roche with regular updates on the progress of the research and development of the Tier 2 Programs at JRT meetings for any pre-ED Go activities and at JDT meetings for any post-ED Go activities.

3.2.5 **Effects of No Option Exercise.** If Roche fails to exercise the Option for a Tier 2 Program before the expiration of the Option Exercise Period (including any extension under Section 3.2.2), Roche shall be deemed to have terminated this Agreement with respect to such Tier 2 Program pursuant to Section 15.5, [***].

3.3 [***]

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[***].

3.4 **Collaboration Programs**

3.4.1 **Initial Collaboration Research Program.** During the Initial Collaboration Research Term, the Parties shall conduct an initial research collaboration program (the “**Initial Collaboration Research Program**”), pursuant to an agreed research plan (the “**Initial Collaboration Research Plan**”), to explore and preclinically test up to six (6) agreed upon scientific hypotheses and/or therapeutic concepts (each such designated hypothesis or concept, a “**Collaboration Research Project**”) involving either (a) the development of potential generally applicable improvements to Allo CAR T-Cell Therapies (“**Collaboration Improvements**”), (b) the prototyping and testing preclinically of a range of new Allo CAR T-Cell Therapies Directed To Target(s) relevant to Heme Malignancy(ies), or (c) the exploration, [***]. For each of the up to six (6) Collaboration Research Projects under the Initial Collaboration Research Program, the Parties will generate a Collaboration Research Data Package to inform Roche’s Collaboration Research Program Designation under Section 3.4.3 and, if applicable, to prioritize any further research and development of Allo CAR T-Cell Therapies in the Additional Collaboration Research

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Program, including prioritization of actual or potential Collaboration Targets, potential clinical combinations and/or design of next-generation Allo CAR T-Cell Therapies. The Initial Collaboration Research Plan, which sets forth the initial [***] Collaboration Research Projects, the requirements for the Collaboration Research Data Package for each such Collaboration Research Project, and the activities to be conducted by the Parties for each such Collaboration Research Project, is attached hereto as Exhibit 3.4.1, as may be amended by the JRT. For Roche, such activities would include [***]. For Poseida, such activities would include leading the cell engineering to develop Collaboration Improvements, prototyping and preclinical testing Allo CAR-T Cell Therapies, and supplying the CAR Cells. Roche and Poseida shall each use Commercially Reasonable Efforts to perform the activities assigned to it under the Initial Collaboration Research Plan within the timelines specified therein. Each Party shall conduct its activities under the Initial Collaboration Research Plan at its own expense and in accordance with the terms and conditions of this Agreement. The Parties shall regularly discuss updates at JRT meetings (or more frequently at Roche's request) regarding the status and progress of each Collaboration Research Project. The Initial Collaboration Research Plan, including all activities thereunder, shall be carried out during the period commencing on [***] (unless the Parties agree otherwise in writing) until twenty-four (24) months thereafter (the "Initial Collaboration Research Term"), and the Initial Collaboration Research Plan shall only assign to Poseida activities that can be completed by Poseida using Commercially Reasonable Efforts within such twenty-four (24) month period. [***].

3.4.2 **Additional Collaboration Research Program.** Roche may elect to add an additional collaboration research program between the Parties ("**Additional Collaboration Research Program**") pursuant to an agreed-upon research plan ("**Additional Collaboration Research Plan**") to explore and preclinically test up to six (6) additional agreed upon scientific hypotheses and/or therapeutic concepts (each such designated hypothesis or concept, an "**Additional Collaboration Research Project**") involving either (a) the development of Collaboration Improvements, (b) the prototyping and testing preclinically of a range of new Allo CAR T-Cell Therapies Directed To Target(s) relevant to Heme Malignancy(ies), or (c) the exploration, [***]. For each of the Additional Collaboration Research Projects, the Parties would generate a Collaboration Research Data Package. The Additional Collaboration Research Plan shall set forth the up to six (6) Additional Collaboration Research Projects, the requirements for the Collaboration Research Data Package for each such Additional Collaboration Research Project, and the activities to be conducted by the Parties for each such Additional Collaboration Research Project. Roche and Poseida shall each use Commercially Reasonable Efforts to perform the activities assigned to it under the Additional Collaboration Research Plan within the timelines specified therein. Each Party shall conduct its activities under the Additional Collaboration Research Plan at its own expense and in accordance with the terms and conditions

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of this Agreement. The Parties shall regularly discuss updates at JRT meetings (or more frequently at Roche's request) regarding the status and progress of each Collaboration Research Project.

Roche may elect to add the Additional Collaboration Research Program by providing written notice to Poseida no later than [***] after the completion of the Initial Collaboration Research Term so long as, at the time of such election, less than six (6) Collaboration Research Programs have been designated pursuant to Section 3.4.3. If Roche elects to add the Additional Collaboration Research Program, the JRT shall draft and approve the Additional Collaboration Research Plan within [***], and following such JRT approval, Roche shall pay Poseida the Additional Collaboration Research Fee as provided in Section 8.4.1. The Additional Collaboration Research Plan, including all activities thereunder, shall be carried out following the expiration of the Initial Collaboration Research Term during the period commencing on the date of the JRT's approval of the Additional Collaboration Research Plan until eighteen (18) months thereafter (the "**Additional Collaboration Research Term**"), and the Additional Collaboration Research Plan shall only assign to Poseida activities that can be completed by Poseida using Commercially Reasonable Efforts within such eighteen (18) month period. [***].

3.4.3 **Collaboration Research Program Designation.** Following receipt of a Collaboration Research Data Package from the Initial Collaboration Research Program, Roche, in its discretion, may designate an Allo CAR T-Cell Therapy that is Directed To designated Heme Malignancy-related Target(s) and includes designated features, including Collaboration Improvement(s) from such Initial Collaboration Research Program, for a further research program by Poseida to identify Collaboration Candidate(s) to commence IND-enabling activities therefor (each such research program, a "**Collaboration Research Program**"). Unless otherwise agreed to by the Parties, Roche may designate up to six (6) Collaboration Research Programs. To designate a Collaboration Research Program, Roche must provide written notice to Poseida describing the Allo CAR T-Cell Therapy, a Target relevant to a Heme Malignancy (including any Tier 1 Target or Tier 2 Target) such designated Allo CAR T-Cell Therapy is Directed To (a "**Collaboration Target**"), and its desired features (including any Collaboration Improvement(s)) (each, a "**Collaboration Research Program Designation**"). With respect to any Collaboration Research Program in which Roche designates an Allo CAR T-Cell Therapy that is Directed To a Collaboration Target that is [***], Poseida may [***], which Roche shall reasonably consider in good faith (but, for clarity, Roche shall not be obligated to agree to such request). Roche must submit all Collaboration Research Program Designations by the later of (a) [***] after receipt of all complete Collaboration Research Data Packages from the Initial Collaboration Research Program or (b) the expiration of the Initial Collaboration Research Term, in each case (a) and (b) unless Roche elects the Additional Collaboration Research Program. If Roche elects the Additional Collaboration Research Program, then Roche must submit all Collaboration Research Program Designations by the later of (c) [***] after receipt of all complete Collaboration Research Data Packages from both the Initial Collaboration Research Program and the Additional Collaboration Research Program or (d) the expiration of the

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Additional Collaboration Research Program. For each Collaboration Research Program Designation, Roche shall pay to Poseida the Collaboration Research Program Designation Fee as provided in Section 8.4.2.

3.4.4 Collaboration Research Program Activities.

(a) **General.** For each Collaboration Research Program, within [***] of the Collaboration Research Program Designation of such Collaboration Research Program, the JRT shall draft and approve an agreed-upon research plan (each, a “Collaboration Research Plan”), which will set forth [***], under the JRT’s oversight. Such activities will include (i) proposing a lead Allo CAR T-Cell Therapy Directed To the Collaboration Target(s) for such Collaboration Research Program (a “Lead Collaboration Candidate”) and [***], (ii) testing the Lead Collaboration Candidate [***] against the ED-Go Candidate Success Criteria, and delivering such test results to the JRT, and (iii) generating an ED-Go Data Package for such Collaboration Research Program demonstrating whether the Lead Collaboration Candidate [***] has met the ED-Go Candidate Success Criteria. Poseida shall use Commercially Reasonable Efforts to perform its activities under each Collaboration Research Plan within the timelines set forth therein [***]. To the extent that Roche in its sole discretion participates in any of the activities pursuant to a Collaboration Research Plan, it shall do so [***]. The Collaboration Research Plan, including all activities thereunder, shall terminate at the end of the applicable Collaboration Research Term.

(b) **ED-Go Decision; Early Development Collaboration Program; Program Transition.** For each Collaboration Research Program and during the Collaboration Research Term, Poseida shall deliver the applicable ED-Go Data Package to the JRT pursuant to the Collaboration Research Plan, and the JRT shall within [***] confirm whether or not the Lead Collaboration Candidate [***] meets the ED-Go Candidate Success Criteria. If the JRT confirms that the Lead Collaboration Candidate [***] has met the ED-Go Success Criteria, then Roche shall decide within [***] of the JRT’s confirmation whether to (i) commence IND-enabling activities and continue development and of such Lead Collaboration Candidate [***] (“**ED-Go Decision**”) or (ii) terminate the applicable Collaboration Research Program. If Roche makes an ED-Go Decision, Roche shall pay Poseida the “ED-Go” milestone for “Program Transition at ED-Go” pursuant to Section 8.6.2. In addition, following such ED-Go Decision, Roche shall elect within the same such [***] period, whether to (A) pursue an early development program under which Poseida would conduct development activities through the Completion of the Phase I DE+ for such Collaboration Research Program (an “**Early Development Collaboration Program**”) pursuant to Section 3.4.6 by providing written notice to Poseida or (B) initiate a Program Transition with respect to such Collaboration Program. The Program Transition Initiation Date for such Collaboration Program for which Roche elects to initiate a Program Transition pursuant to this Section 3.4.4(b) shall occur on the date of Roche’s notice to Poseida to initiate such Program Transition.

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3.4.5 [***]

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[***].

3.4.6 Early Development Collaboration Program.

(a) **General.** Roche may elect to pursue an Early Development Collaboration Program under this Section 3.4.6 for up to [***] Collaboration Research Programs for which at least one (1) Lead Collaboration Candidate [***] achieved the applicable ED-Go Candidate Success Criteria. Within [***] of Poseida's receipt of Roche's notice (pursuant to Section 3.4.4(b)) to elect to pursue an Early Development Collaboration Program, the JDT shall draft and approve an agreed-upon early development plan, including applicable Early Development Candidate Success Criteria and Poseida's activities, under the JDT's oversight, through the Completion of the Phase I DE+ for such Early Development Collaboration Program and a budget therefor (an "**Early Development Collaboration Plan**"). Such activities shall include (a) testing either the Lead Collaboration Candidate [***] for which Roche made an ED-Go Decision (but not more than one Collaboration Candidate) through IND-enabling studies and delivering such test results to the JDT and (b) conducting a Phase I DE+ and generating a Phase I DE+ Data Package for such Early Development Collaboration Program demonstrating whether the applicable Lead Collaboration Candidate [***] met the Early Development Candidate Success Criteria. Poseida shall use Commercially Reasonable Efforts to perform the activities under each Early Development Collaboration Plan within the timelines specified therein. For clarity, except with respect to activities pursuant to [***], Poseida shall not be required to [***] for an Early Development Collaboration Program. Except as otherwise expressly set forth herein, Poseida shall conduct its activities under any Early Development Collaboration Plan [***] but subject to Section 8.4.3. The Early Development Collaboration Plan, including all activities thereunder, shall terminate at the end of the applicable Early Development Collaboration Term.

(b) **Decision; Program Transition.** For each Early Development Collaboration Program and during the Early Development Collaboration Term, Poseida shall deliver the applicable Phase I DE+ Data Package to the JDT pursuant to the Early Development Collaboration Plan, and the JDT shall within [***] confirm whether or not the Lead Collaboration Candidate [***] met the Early Development Candidate Success Criteria. If the JDT confirms that the Lead Collaboration

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Candidate or Back-Up Collaboration Candidate, as applicable, has met the Early Development Candidate Success Criteria, Roche shall elect within [***] of the JDT's confirmation whether to (i) initiate a Program Transition for the applicable Collaboration Program or (ii) terminate such Collaboration Program. If Roche elects to initiate a Program Transition, the Program Transition Initiation Date shall occur on the date of Roche's notice to Poseida to initiate a Program Transition or the lapse of such [***] period.

3.4.7 [***]

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[***].

3.5 Roche Materials

3.5.1 **Transfer.** Roche shall provide Poseida with Materials, if any, as specified to be provided by Roche in the Tier 1 Development Plan, Tier 1 Process Development Plan, Initial Collaboration Research Plan, the Additional Collaboration Research Plan, a Collaboration Research Plan, or an Early Development Collaboration Plan or as agreed by Roche for Poseida's use thereunder through the JRT, JDT, or JMT, as applicable (collectively, the "**Roche Materials**").

3.5.2 **Rights of Use.** With respect to any Roche Materials provided pursuant to this Section 3.5, Poseida shall have the right to use such Roche Materials solely for the activities under the applicable Tier 1 Development Plan, Tier 1 Process Development Plan, Initial Collaboration Research Plan, Additional Collaboration Research Plan, Collaboration Research Plan or Early Development Collaboration Plan. Subject to the foregoing, all such Roche Materials (a) shall be used by Poseida only in accordance with the terms and conditions of this Agreement and the applicable Tier 1 Development Plan, Tier 1 Process Development Plan, Initial Collaboration Research Plan, Additional Collaboration Research Plan, Collaboration Research Plan or Early Development Collaboration Plan; (b) shall not be reverse engineered, deconstructed or analyzed in any way by Poseida except as expressly set forth in the applicable Tier 1 Development Plan, Tier 1 Process Development Plan, Initial Collaboration Research Plan, Additional Collaboration Research Plan, Collaboration Research Plan or Early Development Collaboration Plan; (c) shall not be delivered by such Poseida to any Third Party or used by Poseida for the benefit of any Third Party except as expressly provided for herein (which shall include transfer to Authorized Subcontractors for use in furtherance of the applicable Tier 1 Development Plan, Tier 1 Process Development Plan, Initial Collaboration Research Plan, Additional Collaboration Research Plan, Collaboration Research Plan or Early Development Collaboration Plan); and (d) shall be used by Poseida in compliance with applicable law.

3.5.3 **Ownership.** Roche shall retain all right, title, and interest in and to Roche Materials provided under this Agreement, and the transfer of Roche Materials hereunder shall be a bailment

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and shall not constitute a sale of Roche Materials or a grant, option, or license of any rights under or to any Patent (or other rights) Controlled by Roche other than the limited right of use granted under Section 3.5.2 to Poseida to use the Roche Materials as permitted thereunder.

3.6 **Limitation on Simultaneous Phase I Clinical Development.** The Parties, through the JSC, shall agree upon a prioritization of the Tier 1 Programs, Tier 2 Programs for which Roche exercised an Option Maintenance Election, and Collaboration Programs. Notwithstanding anything to the contrary in Section 3.1, 3.2 or 3.4, unless the Parties otherwise agree, Poseida will not be obligated to simultaneously conduct more than **[***]** Phase I Clinical Trials in which patients are currently being treated at any one time among the Tier 1 Programs, Tier 2 Programs for which Roche exercised an Option Maintenance Election and Early Development Collaboration Programs.

3.7 **Compliance.** Each Party shall perform or cause to be performed any and all of its research and development activities under this Article 3 with respect to a Therapeutic Program in good scientific manner and in compliance with all applicable law and Regulatory Authority requirements.

3.8 **Records.** Each Party shall, and shall ensure that any Third Parties contracted pursuant to Section 6.9, maintain records in sufficient detail and in good scientific manner appropriate for Patent and regulatory purposes, and in compliance with applicable law, which shall be complete and accurate and shall properly reflect all work done and results achieved in the performance of its research and development activities under this Article 3 with respect to a Therapeutic Program, which shall record only such activities and shall not include or be commingled with records of activities other than research and development activities for the Therapeutic Products. All laboratory notebooks shall be maintained for no less than the term of any Patent issuing therefrom. All other records shall be maintained by the applicable Party during the Term in accordance with such Party's standard policies for retention of such records.

ARTICLE 4

Program Transition; Research, Development and Commercialization after Program Transition

4.1 **Program Transition.** After the Program Transition Initiation Date for a Therapeutic Program (unless earlier requested by Roche), Poseida will make the transfers and the Parties will take the other actions described in Sections 4.1.1 through 4.1.2 below (collectively, the "**Program Transition**" for such Therapeutic Program).

4.1.1 **Regulatory Transfer.** No later than **[***]** following the Program Transition Initiation Date for a Therapeutic Program or at such later date **[***]**, Poseida shall, **[***]**, transfer to Roche any INDs relating to the Therapeutic Products for such Therapeutic Program in its possession and control and all clinical and safety databases and other Regulatory Documentation for the applicable Therapeutic Products that are in Poseida's possession and control, **[***]** (the "**Regulatory Transfer**"). If reasonably deemed applicable by Roche, the Parties shall further promptly enter

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into a pharmacovigilance or safety data exchange agreement for the applicable Therapeutic Products for such Therapeutic Program.

4.1.2 **Technology Transfer Preparation.** At Roche's request, Poseida shall promptly facilitate [***]. Technology Transfer shall occur as provided in, and be completed in accordance with, Section 5.4.

4.2 Research, Development and Commercialization following Program Transition

4.2.1 **Roche Right and Responsibility.** For each Therapeutic Program, subject to Poseida's obligation to complete the Program Transition with respect to such Therapeutic Program, following the Program Transition Initiation Date, Roche shall have the sole right and responsibility for all research, development, regulatory affairs and commercialization of Therapeutic Products for the applicable Therapeutic Program, including the sole right and authority to control all decisions related to the research, development, regulatory affairs and commercialization of any Therapeutic Products for such Therapeutic Program.

4.2.2 **Roche Diligence.** For each Therapeutic Program, following completion of Program Transition, Roche shall use Commercially Reasonable Efforts to develop and seek Marketing Authorization [***].

4.2.3 **Supporting Activities.** Without limiting Poseida's obligations hereunder, including the activities allocated to Poseida under the Tier 1 Development Plans, Tier 1 Process Development Plans, Initial Collaboration Research Plan, Additional Collaboration Research Plan, Collaboration Research Plans and Early Development Collaboration Plans and as set forth in Section 4.1.1 and Article 5, Poseida shall provide further consultations with Roche as may be reasonably necessary regarding the research, development, Manufacture, regulatory affairs and commercialization of Therapeutic Products at [***].

4.2.4 **Progress Reports by Roche.** Within [***] after each anniversary of the Effective Date, Roche shall provide to Poseida an annual written report summarizing [***]. Such report shall cover subject matter [***]. After reviewing such report, Poseida may reasonably request additional information regarding the development of the Therapeutic Products through the Alliance Manager, and Roche [***]. On a Therapeutic Program-by-Therapeutic Program basis, Roche's obligations under this Section 4.2.4 shall end upon the First Commercial Sale of such Therapeutic Product [***].

4.3 **Regulatory Affairs.**

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4.3.1 **Prior to Regulatory Transfer.** For each Therapeutic Program, prior to the completion of the Regulatory Transfer for such Therapeutic Program, Poseida shall be responsible for regulatory affairs with respect to such Therapeutic Program, including to the extent required for activities conducted prior to the Program Transition Initiation Date for such Therapeutic Program, for preparing and submitting in its own name, and holding, the initial IND for each Therapeutic Product for such Therapeutic Program until the transfer thereof to Roche as set forth in Section 4.1.1. Poseida shall be responsible for liaising and managing interactions with Regulatory Authorities with respect thereto. In addition, prior to such completion of the Regulatory Transfer for a Therapeutic Program:

(a) **Regulatory Correspondence.** Poseida shall promptly provide to Roche copies of any material documents, information or other correspondence received from a Regulatory Authority pertaining to any Therapeutic Product (including any Phase I Clinical Trial involving such Therapeutic Product) for such Therapeutic Program, including documents, information or other correspondence relating to any and all INDs, IND amendments, Regulatory Authority meeting requests, and Regulatory Authority advice (including scientific advisory packages). Poseida shall provide Roche access to a draft of all materials pertaining to any Therapeutic Product (including any Phase I Clinical Trial involving such Therapeutic Product) for such Therapeutic Program to be submitted by Poseida to a Regulatory Authority, reasonably in advance of the intended submission dates to enable Roche to review and provide comments to Poseida concerning the content thereof. Poseida shall consider in good faith any such comments of Roche.

(b) **Certain Regulatory Correspondence.** In addition to Poseida's obligations under Section 4.3.1(a), Poseida shall within [***], notify Roche in writing of, and provide Roche with copies of, any correspondence and other documentation received or prepared by Poseida in connection with receipt of a clinical hold, warning letter, or similar item from the FDA or any other Regulatory Authority regarding any Therapeutic Product for such Therapeutic Program or in connection with any general cGMP inspections applicable to the Manufacturing facility used by Poseida for any Therapeutic Product for such Therapeutic Program.

(c) **Meetings with Regulatory Authorities.** Poseida shall provide Roche with prior written notice of any substantive meeting, conference, or discussion (including any advisory committee meeting) with a Regulatory Authority relating to any Therapeutic Product for such Therapeutic Program, within [***] after Poseida first receives notice of the scheduling of such meeting (or within such shorter period as may be necessary) in order to give Roche a reasonable opportunity to have a reasonable number, but at least [***] representatives attend such meeting. Roche shall have the right, but not the obligation, to attend and participate in all such meetings (including substantive preparatory pre-meetings with Poseida therefor), to the extent permitted by applicable law and such Regulatory Authority.

(d) **Adverse Event Reports.** Poseida shall be responsible for investigating adverse events and other required safety information associated with the use of any Therapeutic Product for such Therapeutic Program. Poseida shall be responsible for the collection, review, assessment, tracking and filing of information related to adverse events in accordance with applicable law and Regulatory Authority. Poseida shall promptly notify Roche of any serious

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adverse event that requires accelerated regulatory reporting and otherwise keep Roche informed with respect to the same.

4.3.2 **After Regulatory Transfer.** Following the completion of the Regulatory Transfer for a Therapeutic Program, Roche shall thereafter be solely responsible for preparing and submitting Regulatory Documentation for Therapeutic Products for such Therapeutic Program in its own name, including liaising and managing interactions with Regulatory Authorities with respect thereto, [***]; provided that, following such Regulatory Transfer:

(a) [***].

(b) **Support.** Without limiting Poseida's obligations hereunder, including as set forth in Section 4.1.1 and Article 5, at Roche's request, Poseida shall reasonably support Roche, [***], as may be reasonably necessary, in obtaining Marketing Authorization for such Therapeutic Products, including providing necessary documents or other materials required by applicable law and Regulatory Authorities to obtain Marketing Authorization, in each case in accordance with the terms and conditions of this Agreement.

(c) **Adverse Event Reports.** Roche shall be responsible for investigating adverse events and other required safety information associated with the use of any Therapeutic Product for such Therapeutic Program. Roche shall be responsible for the collection, review, assessment, tracking and filing of information related to such adverse events in accordance with applicable law.

ARTICLE 5

Tier 1 Process Development Program; Manufacturing; Technology Transfer

5.1 **Tier 1 Process Development Program.** For each Tier 1 Program, Poseida shall conduct a process development program (each, a "**Tier 1 Process Development Program**"), pursuant to a written plan (each, a "**Tier 1 Process Development Plan**") to optimize the Manufacturing Process for such Tier 1 Program. For each Tier 1 Process Development Program, the JMT shall draft and approve the Tier 1 Process Development Plan within [***] of the formation of the JMT. Each such Tier 1 Process Development Plan shall include the activities to be conducted by Poseida. Poseida shall use Commercially Reasonable Efforts to perform its assigned activities under each Tier 1 Process Development Plan within any timelines set forth therein [***]. To the extent that Roche [***] participates in any of the activities pursuant to the Tier 1 Process Development Plan, it shall do so [***]. For clarity, in no event shall Poseida be required to pay or reimburse Roche for any costs incurred by Roche in connection with any Tier 1 Process Development Program. The Tier 1 Process Development Plan, including all activities thereunder, shall terminate at the end of the Tier 1 Process Development Term.

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5.2 Pre-Clinical and Clinical Supply

5.2.1 Tier 1 Programs.

(a) **Poseida Responsibility for Tier 1 Programs.** For each Tier 1 Program, until completion of the Technology Transfer to Roche pursuant to Section 5.4 for such Tier 1 Program, Poseida shall, subject to the JMT's oversight, be responsible for the pre-clinical and clinical Manufacture and supply of Tier 1 Products for the Parties' activities under this Agreement for such Tier 1 Program, including for the performance of the Tier 1 Development Plan, Tier 1 Process Development Plan, and any assay development or comparability studies requested by a Regulatory Authority prior to the first clinical trial supporting registration of the applicable Tier 1 Product. For clarity, Poseida shall not be responsible for the Manufacture or supply of Tier 1 Products for Phase III Clinical Trials or for commercial use. The cost incurred by Poseida to Manufacture and supply the Tier 1 Products through the Program Transition Initiation Date for such Tier 1 Program shall be [***]. From the Program Transition Initiation Date until the earlier of (i) [***] and (ii) the completion of [***] clinical trial after the Completion of the Phase I DE+, Poseida shall Manufacture and supply [***] the applicable Tier 1 Product(s), and the Parties shall enter into a clinical supply agreement and quality agreement as each relates to Poseida's Manufacture and supply of such Tier 1 Product(s) pursuant to Section 5.2.5.

(b) **Roche Responsibility for Tier 1 Programs.** Following [***] for a Tier 1 Program pursuant to Section 5.3, Roche shall have the sole right and responsibility, at its own expense, for the pre-clinical, clinical, and commercial Manufacture and supply of Tier 1 Products for such Tier 1 Program.

(c) [***].

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5.2.2 Tier 2 Programs.

(a) **Poseida Responsibility for Tier 2 Programs.** For each Tier 2 Program, and until the expiration of the Option Exercise Period (including any extension under Section 3.2.2) or, if Roche has exercised its Option for such Tier 2 Program pursuant to Section 3.2.1 or 3.2.3, as applicable, until Poseida has completed the Technology Transfer to Roche pursuant to Section 5.4 for such Optioned Tier 2 Program, Poseida shall be responsible for the pre-clinical and clinical Manufacture and supply of Tier 2 Candidates for the Parties' activities under this Agreement for such Tier 2 Program. For clarity, Poseida shall not be responsible for the Manufacture or supply of Tier 2 Candidates for Phase III Clinical Trials or for commercial use. The cost incurred by Poseida to Manufacture and supply the Tier 2 Candidates through the Program Transition Initiation Date for such Optioned Tier 2 Program shall be [***]. From the Program Transition Initiation Date until the earlier of (i) [***] and (ii) the completion of the [***] clinical trial after the Program Transition Initiation Date, Poseida shall Manufacture and supply at cost the applicable Tier 2 Candidate(s), and the Parties shall enter into a clinical supply agreement and quality agreement as each relates to Poseida's Manufacture and supply of such Tier 2 Candidate(s) pursuant to Section 5.2.5.

(b) **Roche Responsibility for Optioned Tier 2 Programs.** Following [***] for an Optioned Tier 2 Program pursuant to Section 5.3, Roche shall have the sole right and responsibility, at its own expense, for the pre-clinical, clinical, and commercial Manufacture and supply of Optioned Tier 2 Products for such Optioned Tier 2 Program.

(c) **Manufacturing Process Improvements.** In the course of conducting Manufacturing and supply of Tier 2 Candidates pursuant to this Section 5.2.2, Poseida will, in consultation with the JMT, use Commercially Reasonable Efforts to enable production at scale and [***] for the applicable Manufacturing Process for such Tier 2 Candidates. Poseida will regularly (but not less than [***] each Calendar Quarter) update the JMT on the status of its efforts hereunder.

5.2.3 Initial Collaboration Research Program, Additional Collaboration Research Program and Collaboration Programs.

(a) **Poseida Responsibility for Initial Collaboration Research Program and Additional Collaboration Research Program.** Except for Roche's assigned responsibilities and any Materials that Roche provides, in either case, pursuant to the Initial Collaboration Research Plan and, if applicable, the Additional Collaboration Research Plan, Poseida shall be responsible, [***], for the pre-clinical Manufacture and supply of Collaboration Candidates and Collaboration Products for the Parties' activities under this Agreement for the Initial Collaboration Research Program and the Additional Collaboration Research Program, if applicable, including for the performance of the Initial Collaboration Research Plan or the Additional Collaboration Research Plan, if applicable.

(b) **Poseida Responsibility for Collaboration Programs.** For each Collaboration Program, until [***]

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[***], and subject to the JMT's oversight, Poseida shall be responsible for the pre-clinical and clinical Manufacture and supply of Collaboration Candidates and Collaboration Products for the Parties' activities under this Agreement for such Collaboration Program, including for the performance of such Collaboration Program's Collaboration Research Plan and, if applicable, Early Development Collaboration Plan and Early Development Candidate Remediation Plan and any comparability studies requested by a Regulatory Authority. The costs incurred by Poseida to Manufacture and supply Collaboration Candidates and Collaboration Products through the completion of the Technology Transfer of the applicable Collaboration Program shall be [***], except that [***], which expenses are subject to [***] as provided in Section 8.4.3.

(c) **Roche Responsibility for Collaboration Programs.** Following the completion of the Technology Transfer for a Collaboration Program pursuant to Section 5.4, Roche shall have the sole right and responsibility, at its own expense, for the Manufacture and supply of all Collaboration Candidates and Collaboration Products for such Collaboration Program.

(d) **Manufacturing Process Improvements.** In the course of conducting Manufacturing and supply for each Collaboration Program pursuant to Section 5.2.3(b), Poseida will, in consultation with the JMT, use Commercially Reasonable Efforts to enable production at scale and [***] for the applicable Manufacturing Process for the applicable Collaboration Candidates and Collaboration Products. Poseida will regularly (but not less than [***] each Calendar Quarter) update the JMT on the status of its efforts in accordance with this Section 5.2.3(d).

5.2.4 **Compliance.** Poseida's Manufacturing and supply activities under this Article 5 shall be subject to the oversight and support of the JMT. Poseida shall conduct all of its respective Manufacturing and supply activities hereunder in compliance with all applicable laws, rules and regulations, including cGMP (with respect to clinical supply).

5.2.5 **Clinical Supply Agreement; Quality Agreement.** From the Program Transition Initiation Date until the completion of the Technology Transfer of the applicable Therapeutic Program, Poseida will supply at cost Therapeutic Products for clinical trial(s) sponsored by Roche, and the Parties shall enter into a clinical supply agreement and quality agreement as each relates to Poseida's Manufacture and supply of the applicable Therapeutic Product(s) for the applicable clinical trial(s). The Parties shall use [***] to negotiate and execute such agreements within [***] upon Roche's request to enter into such agreement. Roche shall have the right, at its own cost to conduct audits of any relevant facility and of all suppliers, including any relevant books and records related to such Manufacture and supply of Therapeutic Products prior to execution of any such agreements.

5.3 **Initial Technology Transfer for Tier 1 Programs.**

5.3.1 **P-BCMA-ALLO1 Tier 1 Program.** As promptly as possible after the formation of the JMT, but no later than [***] after such JMT formation, the JMT shall draft and approve an initial technology transfer plan, with respect to the P-BCMA-ALLO1 Tier 1 Program,

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pursuant to which Poseida shall, [***], transfer to Roche (under the JMT's oversight) (a) [***], (b) [***]. Such initial technology transfer plan shall (i) list such documents and Materials to be transferred from Poseida to Roche, (ii) describe the activities to be undertaken by the Parties to facilitate the transfer of such Know-How and (iii) state an estimated timeline and allocation of responsibility with respect to such initial technology transfer, in each case (a)-(c), to denote successful completion of such initial technology transfer under this Section 5.3.

5.3.2 **P-CD19/CD20-ALLO1 Tier 1 Program.** As promptly as possible after the IND of the first Tier 1 Product under the P-CD19/CD20-ALLO1 Tier 1 Program goes into effect in accordance with 21 C.F.R. 312.40(b), but no later than [***] after such IND goes into effect, the JMT shall draft and approve an initial technology transfer plan, with respect to the P-CD19/CD20- ALLO1 Tier 1 Program, pursuant to which Poseida shall, [***], transfer to Roche (under the JMT's oversight) (a) [***], (b) [***]. Such initial technology transfer plan shall (i) list such documents and Materials to be transferred from Poseida to Roche, (ii) describe the activities to be undertaken by the Parties to facilitate the transfer of such Know-How and (iii) state an estimated timeline and allocation of responsibility with respect to such initial technology transfer, in each case (a)-(c), to denote successful completion of such initial technology transfer under this Section 5.3.

5.4 **Technology Transfer.** For each Therapeutic Program, within [***] of the Manufacturing Transition Initiation Date, the JMT shall draft and approve a Technology Transfer Plan. As promptly as possible following the JMT's approval of the Technology Transfer Plan for a Therapeutic Program, Poseida, [***], shall initiate and complete (and cause its Authorized Subcontractors to initiate and complete) a transfer to Roche, or its designee, to the extent not previously disclosed (including under Section 5.3), and in accordance with the applicable Technology Transfer Plan for such Therapeutic Program, as described in this Section 5.4. The transfer obligations described in Sections 5.4.1, 5.4.2, and 5.4.3 collectively, the "**Technology Transfer**":

5.4.1 **Documents Transfer.** Poseida shall effect a full transfer to Roche or its designee of [***]. Such transfer shall include the provision of [***]

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[***].

5.4.2 **Materials Transfer.** Poseida shall, within [***] of Roche's request, assign and transfer to Roche or its designee and deliver or make available to Roche or its designee, [***] inventory of the applicable Therapeutic Product(s) or any other Materials Controlled by Poseida that relate exclusively to the Manufacture of the applicable Therapeutic Product(s), including details of such inventory and Materials to be transferred and the conditions for such transfer. To the extent any such inventory or Materials are in possession of a Third Party, [***].

5.4.3 **Know-How Transfer.** Poseida shall, at a timeline determined by the JMT, effect a full transfer to Roche or its designee of [***]. Such access and assistance shall occur through the JMT, on-site visits at Poseida's or Roche's facilities (or facilities of its Affiliates or designated CMOs, as applicable), or telephonic, videoconference, or other meetings with personnel of Poseida and Authorized Subcontractors. [***].

5.4.4 **Additional Technology Transfer Activities.** Following completion of the Technology Transfer pursuant to the Technology Transfer Plan for the applicable Therapeutic Program until [***] thereafter, [***]. The Parties shall bear the cost of such additional Technology Transfer activities as follows: [***].

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5.5 **Commercial Supply.** Roche shall have the sole right and responsibility, at its own expense, for the commercial Manufacture and supply of Tier 1 Products, Optioned Tier 2 Products and Collaboration Products.

ARTICLE 6 Licenses; Licensed Technologies

6.1 Tier 1 Programs

6.1.1 **Exclusive License from Poseida to Roche.** For each Tier 1 Program, Poseida hereby grants to Roche, effective upon the Effective Date, an exclusive, non-transferable (except as permitted pursuant to Section 17.3), worldwide, royalty-bearing license, including the right to sublicense through multiple tiers (in accordance with Section 6.8), under the Poseida Background IP and Poseida's interest in Joint IP, in each case, to make, use, offer for sale, sell, import, and otherwise fully exploit in the Field the Tier 1 Products.

6.1.2 **Temporary Non-Exclusive Sublicense from Roche to Poseida.** For each Tier 1 Program, Roche hereby grants to Poseida, effective upon the Effective Date, a non-exclusive, non-transferable (except as permitted pursuant to Section 17.3), non-sublicensable sublicense under the license granted to Roche in Section 6.1.1 solely to perform Poseida's obligations under the applicable Tier 1 Development Plan, Tier 1 Process Development Plan, and Manufacturing activities under Sections 5.2.1(a), 5.2.1(c) and 5.2.5 (as applicable) for the applicable Tier 1 Program.

6.2 Tier 2 Programs

6.2.1 **Exclusive License from Poseida to Roche.** For each Optioned Tier 2 Program, Poseida hereby grants to Roche, effective upon the date of receipt of Roche's written notice of exercise of its Option for the applicable Optioned Tier 2 Program pursuant to Section 3.2.1 or 3.2.3, as applicable, (and after the HSR Clearance Date for such Option exercise if Roche determines an HSR Filing is required with respect to such Option exercise), an exclusive, non-transferable (except as permitted pursuant to Section 17.3) worldwide royalty-bearing license, including the right to sublicense through multiple tiers (in accordance with Section 6.8), under the Poseida Background IP and Poseida's interest in Joint IP, in each case, to make, use, offer for sale, sell, import, and otherwise fully exploit in the Field the Optioned Tier 2 Products for such Optioned Tier 2 Program.

6.2.2 **Temporary Non-Exclusive Sublicense from Roche to Poseida.** For each Optioned Tier 2 Program, Roche hereby grants to Poseida, effective upon the effective date of Roche's license for the applicable Optioned Tier 2 Program pursuant to Section 6.2.1, as applicable, a non-exclusive, non-transferable (except as permitted pursuant to Section 17.3), non-sublicensable license sublicense under the license granted to Roche in Section 6.2.1 solely to perform Poseida's Manufacturing obligations under Sections 5.2.2(a), 5.2.2(c) and 5.2.5 (as applicable) for the applicable Optioned Tier 2 Program.

6.3 Collaboration Programs

6.3.1 Poseida to Roche.

(a) **Research Stage License.** Poseida hereby grants to Roche, effective upon the Effective Date, a non-exclusive, non-transferable (except as permitted pursuant to Section 17.3), worldwide license, including the right to sublicense through multiple tiers (in accordance with Section 6.8), under the Poseida Background IP solely to perform the activities allocated to Roche under the Initial Collaboration Research Plan during the Initial Collaboration Research Term (and if applicable, under the Additional Collaboration Research Plan during the Additional Collaboration Research Term).

(b) **Commercial License.** For each Collaboration Program, Poseida hereby grants to Roche, effective upon Collaboration Research Program Designation of the applicable Collaboration Program (and after the HSR Clearance Date for such Collaboration Research Program Designation if Roche determines an HSR Filing is required with respect to such Collaboration Research Program Designation), an exclusive, non-transferable (except as permitted pursuant to Section 17.3), worldwide and royalty-bearing license, including the right to sublicense through multiple tiers (in accordance with Section 6.8), under the Poseida Background IP and Poseida's interest in Joint IP, in each case, to make, use, offer for sale, sell, import, and otherwise fully exploit in the Field the Collaboration Products from such Collaboration Program.

6.3.2 Roche to Poseida.

(a) **Research Stage License.** Roche hereby grants to Poseida, effective upon the Effective Date, a non-exclusive, non-transferable (except as permitted pursuant to Section 17.3), non-sublicensable, worldwide license under the Roche Background IP to perform the activities allocated to Poseida under the Initial Collaboration Research Plan during the Initial Collaboration Research Term (and if applicable, under the Additional Collaboration Research Plan during the Additional Collaboration Research Term) and Poseida's Manufacturing obligations under Section 5.2.1(a).

(b) **Temporary Collaboration Program License and Sublicense.** For each Collaboration Program, Roche hereby grants to Poseida, effective upon Collaboration Research Program Designation of the applicable Collaboration Program, a non-exclusive, non-transferable (except as permitted pursuant to Section 17.3), non-sublicensable worldwide sublicense under the Roche Background IP and the license granted to Roche in Section 6.3.1(b), in all cases, solely to perform Poseida's obligations under the applicable Collaboration Research Plan or, if applicable, Early Development Collaboration Plan and Poseida's Manufacturing obligations under Sections 5.2.3 and 5.2.5 (as applicable).

6.4 [***]

[***] = Certain Confidential Information Omitted

[***].

6.5 [***].

6.6 Licensed Technologies

6.6.1 Initial Evaluation License.

(a) **License.** Effective upon the later of the Effective Date or [***] (unless the Parties agree otherwise in writing) and terminating [***] after the date of Roche's receipt of Poseida's notice of the of the Initial Licensed Technologies Transfer (the "**Initial Research License Term**"), Poseida hereby grants to Roche a non-exclusive, non-transferable (except as permitted pursuant to Section 17.3), sublicensable to Affiliates only (in accordance with Section 6.8), worldwide license under the (i) Cas-CLOVER Gene Editing IP, (ii) Tscm-Enabling IP, and (iii) the Donor Selection IP (collectively, the "**Licensed Technologies**") solely to perform research activities pursuant to the study plan attached hereto as Exhibit 6.6.1(a), as may be amended upon agreement of the Parties (the "**Study Plan**").

(b) **Limited Initial Licensed Technologies Transfer.** Poseida shall provide to Roche, within [***] of the commencement of the Initial Research License Term, the [***] (the "**Initial Licensed Technologies Transfer**"). Poseida shall provide written notice to Roche upon completion of the Initial Licensed Technologies Transfer.

6.6.2 Research and Development License.

(a) **Option for Extended Research and Development License.** Poseida hereby grants to Roche a non-exclusive option, exercisable at any time during the Initial Research License Term, for the non-exclusive, research and development license under the Licensed Technologies set forth in Section 6.6.2(b) and for a full technology transfer with respect to the Licensed Technologies as provided in Section 6.6.2(c) (the "**R&D License Option**"). Roche may

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exercise the R&D License Option by providing written notice to Poseida of its election during the Initial Research License Term. If Roche provides such notice, Roche shall pay the R&D License Fee to Poseida as provided in Section 8.5.1.

(b) **License.** Effective from the date of exercise by Roche of the R&D License Option pursuant to Section 6.6.2(a) and terminating on the [***] of such date (the “**R&D License Term**”), Poseida hereby grants to Roche a non-exclusive, non-transferable (except as permitted pursuant to Section 17.3), worldwide license, including the right to sublicense through multiple tiers (in accordance with Section 6.8), under the Licensed Technologies to research, develop, and manufacture (but not commercialize) Off-The-Shelf TCR-Expressing Cell Therapies Directed To a Licensed Target and Personalized TCR-Expressing Cell Therapies (the “**R&D License**”).

(c) **Full Licensed Technologies Transfer.** Promptly following the date of Roche’s exercise of the R&D License Option pursuant to Section 6.6.2(a) or at such later date as requested by Roche, Poseida will, [***] for the first [***] FTE hours of technology transfer services, initiate and complete a technology transfer to Roche (the “**Full Licensed Technologies Transfer**”) of [***] (“**Licensed Technologies Know-How**”). [***]. Notwithstanding the foregoing, Poseida shall not be required to transfer any Know-How pursuant to this Section 6.6.2(c) if such Know-How has previously been provided by Poseida to Roche for pursuant to the Initial Licensed Technologies Transfer or if such Know-How is not within the Licensed Technologies. [***].

(d) **Designation of a Licensed Target for Off-The-Shelf TCR-Expressing Cell Therapies;** [***]. During the R&D License Term, Roche may, under the R&D License, use the Licensed Technologies to research, develop, and manufacture (but not commercialize) Off- The-Shelf TCR-Expressing Cell Therapies, but only those Directed To a Licensed Target. For clarity, [***]. With respect to Off-The-Shelf TCR-Expressing Cell Therapies, Roche may nominate, in accordance with this Section 6.6.2(d), a Target directed to a solid tumor (each, a “**Proposed Target**”) either to add as a Licensed Target [***]. To nominate a Proposed Target, Roche shall provide written notice to Poseida through Poseida’s Alliance Manager with the identity of such Proposed Target and its intent to nominate such Proposed Target either to add as a Licensed Target [***]

[***] = Certain Confidential Information Omitted

[***] (such notice, a “**Nomination**”). All Nominations, including [***], must be submitted prior to the expiration of the R&D License Term, [***].

6.6.3 [***].

6.6.4 **Commercial License**

(a) **Commercial License Option.** Poseida hereby grants to Roche a non- exclusive option, exercisable at any time during the R&D License Term, for the non-exclusive, commercial license under the Licensed Technologies set forth in Section 6.6.4(b) (the “**Commercial License Option**”). Roche may exercise the Commercial License Option by providing written notice to Poseida of its election during the R&D License Term (the “**Commercial License Option Exercise**”). If Roche provides such notice, Roche shall pay the Commercial License Fee to Poseida as provided in Section 8.5.2.

(b) **License.** Effective upon the date of Commercial License Option Exercise, Poseida hereby grants to Roche a non-exclusive, non-transferable (except as permitted pursuant to Section 17.3), royalty-bearing, worldwide license, including the right to sublicense through multiple tiers (in accordance with Section 6.8), under the Licensed Technologies to make, modify, use, offer for sale, sell, import, and otherwise fully exploit Licensed Products (the “**Commercial License**”).

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(c) **Designated Licensed Targets.** The Commercial License Option and payment of the Commercial License Fee by Roche shall entitle Roche to designate one (1) of the then-existing Licensed Targets as a “**Designated Licensed Target**”, to which the Commercial License with respect to Off-The-Shelf TCR-Expressing Cell Therapies will apply, by providing written notice to Poseida concurrently with the Commercial License Option Exercise. At any time during the R&D License Term, Roche may further designate additional Licensed Target(s) as Designated Licensed Target(s) to which the Commercial License with respect to Off-The-Shelf TCR-Expressing Cell Therapies will apply, by providing written notice to Poseida of the additional Licensed Target to be added as a Designated Licensed Target. For each such additional Designated Licensed Target, Roche shall pay a Target Extension Fee to Poseida as provided in Section 8.5.3. Effective upon the date of Poseida’s receipt of written notice from Roche identifying the Licensed Target to be added as a Designated Licensed Target. The Commercial License may be expanded under this Section 6.6.4(c) to allow for a maximum of three (3) Designated Licensed Targets with respect to Off-The-Shelf TCR-Expressing Cell Therapies. For clarity, the Commercial License for Personalized TCR-Expressing Cell Therapies is not subject to the Designated Licensed Target restriction.

6.7 **Additional Know-How.** [***], at least [***] each Calendar Year for the first [***] after the Effective Date and then [***] each Calendar Year thereafter (or such other frequency as mutually agreed by the Parties), Poseida shall provide to Roche (or the JRT, JDT, or JMT as appropriate) any and all [***] (each provision of such additional Know-How, a “**Technical Update**”), [***]. Notwithstanding the foregoing, at any time during the Term, Roche may (a) request that Poseida limit the scope of disclosure of a Technical Update, which request may be withdrawn in a subsequent Technical Update, and (b) terminate its right to receive future Technical Updates by written notice to Poseida.

6.8 **Sublicenses by Roche.** Roche shall have the right to sublicense the rights granted under Sections 6.1.1, 6.2.1, 6.3.1, 6.6.1, 6.6.2(a), 6.6.2(b) and 6.6.4(b) to its Affiliates and Third Party subcontractors or bona fide collaborators; provided that such sublicense is subject to and consistent with the terms and conditions of this Agreement, and provided further that Roche shall remain responsible for such Affiliate’s or Third Party’s compliance with all obligations under this Agreement applicable to such Affiliate or Third Party. In the case of any sublicense granted by Roche under the licenses granted under Section 6.6.2(b) or Section 6.6.4(b), Roche shall have the right to grant such sublicense only in connection with the grant of a license to Patents or Know- How owned or licensed by Roche or its Affiliates and for the development and commercialization of Licensed Products.

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6.9 Subcontracting.

6.9.1 **Subcontractors.** Roche shall have the right to subcontract any of its activities under this Agreement to a Third Party. Poseida shall not subcontract any material activities under a Tier 1 Development Plan, Tier 1 Process Development Plan, Initial Collaboration Research Plan, Additional Collaboration Research Plan, Collaboration Research Plan, Early Development Collaboration Plan, or Manufacturing activities, to a Third Party, other than to the applicable Authorized Subcontractor. The activities performed by an Authorized Subcontractor on behalf of Poseida shall be pursuant to a written subcontract specifying the work to be subcontracted, and containing provisions consistent with the terms and conditions of this Agreement, including with respect to confidentiality and intellectual property. Poseida shall provide Roche the opportunity to review any such subcontract prior to its execution.

6.9.2 **Performance.** Each Party shall be responsible (and liable) to the other Party for the performance of such Party's activities pursuant to this Agreement by its subcontractors and for any failure by its subcontractors to comply with the restrictions, limitations and obligations set forth in this Agreement as if such performance or failure of such subcontractors were the performance or failure of such Party under this Agreement.

6.10 Third Party Licenses.

6.10.1 **Third-Party In-License Agreement Obligations.** The terms of this Agreement, including the licenses and rights granted to Roche hereunder and Article 12, are subject in all respects to the terms of the Third Party In-License Agreements, and Roche shall comply with such terms, (a) [\[***\] or \(b\) accepted by Roche pursuant to the proviso in the definition of Control in Section 1.61 as reasonably agreed by the Parties. \[***\]](#).

6.10.2 **Cooperation.** Notwithstanding Poseida's obligation of non-disclosure of Roche's Confidential Information set forth in Section 10.3, Poseida shall have the right to share information contained in any final royalty report accompanying a royalty payment (or related to milestones or payments received), progress report or information disclosed in connection with patent prosecution, maintenance, enforcement or defense of a Patent licensed under the applicable Third Party In-License Agreement, or indemnification delivered by Roche under this Agreement solely to the extent necessary to fulfill its reporting obligations under any Third Party In-License Agreement [***], provided that Poseida (a) may disclose only such information that is required to fulfill such reporting obligations as advised by its legal counsel, (b) shall provide Roche with a copy of the intended disclosure reasonably in advance for Roche to review and comment prior to such disclosure (which comments Poseida shall reasonably consider in good faith), provided that Poseida shall have no obligation to provide any information in such disclosure that was not provided by Roche, (c) shall only share such information with the counterparty under the relevant Third Party In-License Agreement subject to a written obligation of confidentiality, and (d) if applicable, shall enter into a common interest agreement or joint defense agreement to maintain any applicable legal privileges. Roche shall reasonably cooperate with Poseida to ensure compliance with the terms [***] to the extent arising out of Roche activities under this Agreement.

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6.10.3 **Excluded Third Party In-License Agreements.** Notwithstanding anything to the contrary herein, the licenses granted by Poseida hereunder as of the Effective Date do not grant to Roche rights or licenses under the Excluded Third Party In-License Agreements.

6.11 **Change in Control.** Notwithstanding anything in this Agreement to the contrary, following the closing of a Change in Control of Poseida, [***].

6.12 **No Additional Licenses.** Except as expressly provided in this Agreement, nothing in this Agreement shall grant either Party any right, title or interest in and to the Know-How, Patents or other intellectual property rights of the other Party (either expressly or by implication or estoppel) and all rights not specifically granted herein are reserved to and retained by the possessing Party.

ARTICLE 7 Exclusivity

7.1 Exclusivity

7.1.1 **Tier 2 Programs.** Subject to Section 7.2, for each Tier 2 Program, [***], Poseida shall not itself, or through or with any of its Affiliates, directly or indirectly, [***]

[***] = Certain Confidential Information Omitted

[***].

7.1.2 Initial Collaboration Research Programs; Additional Collaboration Research

Programs. Subject to Section 7.2, [***], Poseida shall not itself, or through or with any of its Affiliates, directly or indirectly, research, develop, or commercialize, or authorize, enable, or license any Third Party to [***].

7.1.3 Tier 1 Programs, Optioned Tier 2 Programs, and Collaboration Programs.

Subject to Section 7.2, for each (a) Tier 1 Program, from the Effective Date, (b) Optioned Tier 2 Program, from the exercise of the applicable Option, and (c) Collaboration Program, from Collaboration Research Program Designation, until [***], Poseida shall not itself, or through or with any of its Affiliates, directly or indirectly, [***].

7.2 Exceptions.

7.2.1[***]

7.2.2 Change in Control.

If a Third Party becomes an Affiliate of Poseida after the Effective Date through merger, acquisition, stock or asset sale or other similar transaction (each, an “**Acquisition Affiliate**”), then, with respect to each Acquisition Affiliate’s activities that, if

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conducted by Poseida, would cause Poseida to be in breach of its exclusivity obligations set forth in Section 7.1 (such activities, a “**Competing Program**”):

[***].

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ARTICLE 8 Financial Terms

8.1 **Upfront Payment.** In consideration for the rights and licenses set forth herein, no later than thirty (30) days after Roche's receipt of an invoice therefor from Poseida promptly issued following the Effective Date, Roche shall pay Poseida a one-time, non-creditable, non-refundable upfront payment in the amount of one hundred ten million US Dollars (\$110,000,000).

8.2 Tier 1 Programs

8.2.1 **Reimbursement of Certain Tier 1 Development Expenses.** For each Tier 1 Program, Roche shall reimburse [***] of the FTE Costs and Out-of-Pocket Costs incurred by Poseida after the Execution Date in the performance of its Tier 1 Activities under and in accordance with the applicable Tier 1 Development Plan (for the avoidance of doubt, [***] up to a maximum reimbursement cap of twenty million US Dollars (\$20,000,000) for each Tier 1 Program. Any Tier 1 Development Expenses incurred by Poseida for each Tier 1 Program in excess of the foregoing cap for such Tier 1 Program shall be [***]. Until the foregoing cap for such Tier 1 Program has been reached, Poseida shall provide to Roche with regard to such Tier 1 Program, an invoice for Roche's reimbursable share of the Tier 1 Development Expenses within [***] following the end of the Calendar Quarter in which such Tier 1 Development Expenses were incurred, accompanied by a written report summarizing all Tier 1 Development Expenses for the applicable Tier 1 Program during such Calendar Quarter and calculating the amount thereof reimbursable by Roche under this Section 8.2.1. [***]

-
[***] = Certain Confidential Information Omitted

[***].

8.2.2 [***]:

Tier 1 Program	P-BCMA-ALLO1	P-CD19/CD20-ALLO1
[***]	[\$***]	[\$***]

[***].

8.3 Tier 2 Programs

8.3.1 **Option Exercise Fees.** For each Tier 2 Program for which Roche provides written notice to Poseida to exercise its Option pursuant to either Section 3.2.1 or 3.2.3, Roche shall pay Poseida the following one-time, non-creditable, non-refundable, Option exercise fee corresponding to the stage in development when such Option is exercised (an “**Option Exercise Fee**”):

Stage of Development at Time of Exercise	ED-Go Decision	Phase I DE+
Option Exercise Fee	[\$***]	[\$***]

Poseida shall invoice Roche for the applicable Option Exercise Fee after receipt of written notice from Roche of its exercise of its Option pursuant to Section 3.2.1 or 3.2.3, and Roche will pay Poseida within [***] of receipt of an undisputed invoice from Poseida with respect thereto.

8.3.2 **Option Maintenance Fees.** For each Tier 2 Program for which Roche does not exercise its Option at “ED-Go” but instead provides written notice to Poseida to elect to extend the Option Exercise Period pursuant to Section 3.2.2, Roche shall pay Poseida a one-time, non-creditable, non-refundable option maintenance fee in the amount of [***] (an “**Option Maintenance Fee**”). Poseida shall invoice Roche for the Option Maintenance Fee after receipt of written notice from Roche of its election to extend the Option Exercise Period pursuant to Section 3.2.2, and Roche will pay Poseida within [***] of receipt of an undisputed invoice from Poseida with respect thereto.

8.4 Collaboration Programs.

8.4.1 **Additional Collaboration Research Fee.** If Roche elects to add the Additional Collaboration Research Program pursuant to Section 3.4.2, Roche shall pay Poseida a one-time,

[***] = Certain Confidential Information Omitted

non-creditable, non-refundable, fee in the amount of [***] (the “**Additional Collaboration Research Fee**”). Poseida shall invoice Roche for the Additional Collaboration Research Fee after written notice from Roche of its election to add the Additional Collaboration Research Program pursuant to Section 3.4.2, and Roche will pay Poseida within [***] of receipt of an undisputed invoice from Poseida with respect thereto.

8.4.2 **Collaboration Research Program Designation Fee.** If Roche designates a Collaboration Research Program pursuant to Section 3.4.3, Roche shall pay Poseida a one-time, non-creditable, non-refundable, fee for each such Collaboration Research Program in the amount of [***] (each, a “**Collaboration Research Program Designation Fee**”). Poseida shall invoice Roche for the Collaboration Research Program Designation Fee after receiving Roche’s Collaboration Research Program Designation pursuant to Section 3.4.3, and Roche will pay Poseida within [***] of receipt of an undisputed invoice from Poseida with respect thereto.

8.4.3 **Reimbursement of a Portion of Early Development Collaboration Program Expenses.** For each Collaboration Program for which Roche elects to pursue an Early Development Collaboration Program under Section 3.4.4(b) or 3.4.6, Roche shall reimburse [***] of the FTE Costs, Out-of-Pocket Costs, and [***] actually incurred by Poseida in the performance of its activities under the Early Development Collaboration Plan and any Early Development Candidate Remediation Plan each in accordance with the budgets included therein (collectively, the “**Early Development Collaboration Expenses**”). For clarity, in no event shall Roche be obligated under this Section 8.4.3 to reimburse Poseida more than [***] of the budget set forth in the Early Development Collaboration Plan or Early Development Candidate Remediation Plan, as applicable. For each Early Development Collaboration Program, Poseida shall provide to Roche an invoice for any Early Development Collaboration Expenses within [***] following the end of the Calendar Quarter in which such Early Development Collaboration Expenses were incurred accompanied by a written report summarizing all such Early Development Collaboration Expenses incurred in such Calendar Quarter and calculating the amount thereof reimbursable by Roche under this Section 8.4.3. [***]

[***] = Certain Confidential Information Omitted

[***].

8.5 Licensed Technologies.

8.5.1 **R&D License Fee.** If Roche elects to exercise the R&D License Option pursuant to Section 6.6.2(a), Roche shall pay Poseida a one-time, non-creditable, non-refundable research and development license fee in the amount of [***] (the “**R&D License Fee**”). Poseida shall invoice Roche for the R&D License Fee after written notice from Roche of its election to exercise the R&D License Option pursuant to Section 6.6.2(a), and Roche will pay Poseida within [***] of receipt of an undisputed invoice from Poseida with respect thereto.

8.5.2 **Commercial License Fee.** If Roche exercises the Commercial License Option set forth in Section 6.6.4(a) with respect to Off-The-Shelf TCR-Expressing Cell Therapies Directed To a particular Licensed Target (which shall become a Designated Licensed Target as a result of such exercise) and Personalized TCR-Expressing Cell Therapies, Roche shall pay Poseida a one-time, non-creditable, non-refundable commercial license fee in the amount of [***] (“**Commercial License Fee**”). Poseida shall invoice Roche for the Commercial License Fee after written notice from Roche of its election to exercise the Commercial License Option pursuant to Section 6.6.4(a), and Roche will pay Poseida within [***] of receipt of an undisputed invoice from Poseida with respect thereto.

8.5.3 **Target Extension Fee.** If Roche elects to expand the scope of the license granted pursuant to Section 6.6.4(b) to add up to [***] additional Designated Licensed Targets as described in Section 6.6.4(c), Roche shall pay Poseida a non-creditable, non-refundable target extension fee for each additional Designated Licensed Target (each, a “**Target Extension Fee**”) in the amount of [***]. Poseida may invoice Roche for a Target Extension Fee after written notice from Roche of its election to add an additional Licensed Target as a Designated Licensed Target pursuant to Section 6.6.4(c), and Roche will pay Poseida within [***] of receipt of an undisputed invoice from Poseida with respect thereto.

8.6 Development and Regulatory Milestones.

8.6.1 **Tier 1 Programs; Optioned Tier 2 Programs.** For each Tier 1 Program or Optioned Tier 2 Program, Roche shall pay Poseida each applicable non-creditable, non-refundable milestone payment set forth in the following table, in accordance with Section 9.1.1, following the first achievement of the corresponding milestone event for such Tier 1 Program or Optioned Tier 2 Program, as applicable:

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Milestone Event	P-BCMA-ALLO1 Program	P-CD19/CD20-ALLO1 Program	Optioned Tier 2 Program with Option exercise at Completion of Phase I DE+ (pursuant to Section 3.2.3)	Optioned Tier 2 Program with Option exercise at ED-Go (pursuant to Section 3.2.1)
[***]	[***]	[***]	[***]	\$[***]
[***]	\$[***]	\$[***]	[***]	[***]
[***]	\$[***]	\$[***]	[***]	\$[***]
[***]	\$[***]	\$[***]	\$[***]	\$[***]
[***]	\$[***]	\$[***]	\$[***]	\$[***]
[***]	\$[***]	\$[***]	\$[***]	\$[***]
[***]	\$[***]	\$[***]	\$[***]	\$[***]
[***]	\$[***]	\$[***]	\$[***]	\$[***]
[***]	\$[***]	\$[***]	\$[***]	\$[***]
[***]	\$[***]	\$[***]	\$[***]	\$[***]

[***]. For the avoidance of doubt, Roche’s cumulative obligation under this Section 8.6.1 shall in no event exceed: (a) for the P-BCMA-ALLO1 Tier 1 Program, [***]; (b) for the P-CD19/CD20 Tier 1 Program, [***]; (c) for each Optioned Tier 2 Program for which

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Roche exercises its Option the Completion of Phase I DE+, [***]; and (d) for each Optioned Tier 2 Program for which Roche exercises its Option at “ED-Go”, [***].

As used herein, [***] for which the same milestone has not been achieved previously, and does not need to be the same for each milestone. For example, the milestone for [***] for a [***] and the milestone for [***] for a [***] may be achieved in [***]. For clarity, if either a Tier 1 Product [***] or an Optioned Tier 2 Product [***] achieves the “[***]” milestone, then the same Tier 1 Product [***] or Optioned Tier 2 Product [***] is eligible to achieve the “[***]” only if (i) such [***] is tested in an [***] tested in achieving the “[***]” milestone and (ii) such “[***]” milestone has not already been achieved by the applicable Tier 1 Product or Optioned Tier 2 Product [***].

8.6.2 **Collaboration Programs.** For each Collaboration Program, Roche shall pay Poseida each non-creditable, non-refundable, milestone payment set forth in the following table, in accordance with Section 9.1.1, following the first achievement of the corresponding milestone event for such Collaboration Program:

Milestone Event	Program Transition at Completion of Phase I DE+ (pursuant to Section 3.4.6(b))	Program Transition at ED-Go (pursuant to Section 3.4.4(b))
[***]	\$[***]	\$[***]
[***]	\$[***]	\$[***]
[***]	\$[***]	\$[***]
[***]	\$[***]	\$[***]
[***]	\$[***]	\$[***]
[***]	\$[***]	\$[***]
[***]	\$[***]	\$[***]
[***]	\$[***]	\$[***]
[***]	\$[***]	\$[***]

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Milestone Event	Program Transition at Completion of Phase I DE+ (pursuant to Section 3.4.6(b))	Program Transition at ED-Go (pursuant to Section 3.4.4(b))
[***]		

[***]. For the avoidance of doubt, Roche’s cumulative obligation under this Section 8.6.2 shall in no event exceed: (a) for each Collaboration Program for which Program Transition occurs at the Completion of the Phase I DE+, [***] and (b) for each Collaboration Program for which Program Transition occurs at “ED-Go”, [***]. For clarity, if a Collaboration Product [***] achieves the “[***]” milestone, then the same Collaboration Product [***] is eligible to achieve the “[***]” only if (i) such [***] tested in achieving the “[***]” milestone and (ii) such “[***]” milestone has not already been achieved by the applicable Tier 1 Product or Optioned Tier 2 Product [***].

8.6.3 Licensed Products.

(a) **Autologous Licensed Products.** Roche shall pay Poseida each non- creditable, non-refundable, milestone payment set forth in the following table, in accordance with Section 9.1.1, following the first achievement of the corresponding milestone event by an Autologous Licensed Product that is [***]:

Milestone Event	Milestone Payment
[***]	\$[***]
[***]	\$[***]
[***]	\$[***]
[***]	\$[***]

[***]. For the avoidance of doubt, Roche’s cumulative obligation under this Section 8.6.3(a) shall in no event exceed: (I) [***] for Autologous Licensed Products that are [***], (II) for each Designated Licensed Target, [***] for Autologous Licensed Products that are [***]

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[***] Directed To such Designated Licensed Target, and (III) if there are [***] Designated Licensed Targets, [***] for all [***] Directed To any Designated Licensed Target.

(b) **Allogeneic Licensed Products.** Roche shall pay Poseida each milestone payment set forth in the following table, in accordance with Section 9.1.1, following the first achievement of the corresponding milestone event by an Allogeneic Licensed Product that is [***]:

Milestone Event	Milestone Payment
[***]	\$[***]
[***]	\$[***]
[***]	\$[***]
[***]	\$[***]

[***]. For the avoidance of doubt, Roche’s cumulative obligation under this Section 8.6.3(b) shall in no event exceed: (I) [***] for Allogeneic Licensed Products that are [***] and (II) for each Designated Licensed Target, [***] for Allogeneic Licensed Products that are [***] Directed To such Designated Licensed Target and (III) if there are [***] Designated Licensed Targets, [***] for all [***] Directed To such [***] Designated Licensed Targets.

8.6.4 **Skipped Milestones.** If any [***] under Section 8.6.1, 8.6.2, 8.6.3(a) or 8.6.3(b) is skipped because no [***], then the applicable skipped milestone event will be deemed achieved at the time of [***], and the corresponding milestone payment for such skipped milestone event(s) will be paid at the time of [***]

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[***].

8.7 **Net Sales Milestones.**

8.7.1 **Tier 1 Programs; Optioned Tier 2 Programs.** For each Tier 1 Program and Optioned Tier 2 Program, Roche shall pay Poseida each non-creditable, non-refundable milestone payment set forth in the following table, in accordance with Section 9.1.2, following the first achievement of the applicable milestone event by a Tier 1 Product of such Tier 1 Program or Optioned Tier 2 Product of such Optioned Tier 2 Program, respectively:

Milestone Event (based on worldwide Annual Net Sales of a single Tier 1 Product or a single Optioned Tier 2 Product)	Tier 1 Programs	Optioned Tier 2 Programs with Option exercise at Completion of Phase I DE+ (pursuant to Section 3.2.3)	Optioned Tier 2 Programs with Option exercise at ED-Go (pursuant to Section 3.2.1)
Worldwide Annual Net Sales [***]	\$[***]	\$[***]	\$[***]
Worldwide Annual Net Sales [***]	\$[***]	\$[***]	\$[***]
Worldwide Annual Net Sales [***]	\$[***]	\$[***]	\$[***]

[***]. For the avoidance of doubt, Roche’s cumulative obligation under this Section 8.7.1 shall in no event exceed: (a) for each Tier 1 Program, [***]; (b) for each Optioned Tier 2 Program for which Roche exercises its Option at the Completion of Phase I DE+, [***]; and (c) for each Optioned Tier 2 Program for which Roche exercises its Option at “ED-Go”, [***].

8.7.2 **Collaboration Programs.** For each Collaboration Program, Roche shall pay Poseida each non-creditable, non-refundable milestone payment set forth in the following table, in accordance with Section 9.1.2, following the first achievement of the applicable milestone event by a Collaboration Product of such Collaboration Program:

Milestone Event (based on worldwide Annual Net Sales of a single Collaboration Product)	Program Transition at Completion of Phase I DE+ (pursuant to Section 3.4.4(b))	Program Transition at ED-Go (pursuant to Section 3.4.6(b))
Worldwide Annual Net Sales [***]	\$[***]	\$[***]

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Milestone Event (based on worldwide Annual Net Sales of a single Collaboration Product)	Program Transition at Completion of Phase I DE+ (pursuant to Section 3.4.4(b))	Program Transition at ED-Go (pursuant to Section 3.4.6(b))
Worldwide Annual Net Sales [***]	\$[***]	\$[***]
Worldwide Annual Net Sales [***]	\$[***]	\$[***]

[***]. For the avoidance of doubt, Roche’s cumulative obligation under this Section 8.7.1 shall in no event exceed: (a) for each Collaboration Program for which Program Transition occurs at the Completion of Phase I DE+, [***], and (b) for each Collaboration Program for which Program Transition occurs at “ED-Go”, [***].

8.7.3 Licensed Products.

(a) **Autologous Licensed Products.** Roche shall pay Poseida each non- creditable, non-refundable milestone payment set forth in the following table, in accordance with Section 9.1.2, following the first achievement of the corresponding milestone event for Autologous Licensed Products that are [***]:

Milestone Event [***]	Milestone Payment
Worldwide Annual Net Sales [***]	\$[***]
Worldwide Annual Net Sales [***]	\$[***]
Worldwide Annual Net Sales [***]	\$[***]

[***]. For the

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avoidance of doubt, Roche’s cumulative obligation under this Section 8.7.3(a) shall in no event exceed: (I) [***] for Autologous Licensed Products that are [***], (II) for each Designated Licensed Target, [***] for Autologous Licensed Products that are [***] Directed To such Designated Licensed Target, and (III) if there are [***] Designated Licensed Targets, [***] for all Autologous Licensed Products that are [***] Directed To such [***] Designated Licensed Targets.

(b) **Allogeneic Licensed Products.** Roche shall pay Poseida each non- creditable, non-refundable milestone payment set forth in the following table, in accordance with Section 9.1.2, following the first achievement of the corresponding milestone event for Allogeneic Licensed Products that are [***]:

Milestone Event [***]	Milestone Payment
Worldwide Annual Net Sales [***]	\$[***]
Worldwide Annual Net Sales [***]	\$[***]
Worldwide Annual Net Sales [***]	\$[***]

[***]. For the avoidance of doubt, Roche’s cumulative obligation under this Section 8.7.3(b) shall in no event exceed: (I) [***] for Allogeneic Licensed Products that are [***], (II) for each Designated Licensed Target, [***] for Allogeneic Licensed Products that are [***] Directed To such Designated Licensed Target, and (III) if there are [***] Designated Licensed Targets, [***] for all Allogeneic Licensed Products that are [***] Directed To such [***] Designated Licensed Targets.

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8.8 **Royalties.**

8.8.1 **Tier 1 Products; Optioned Tier 2 Products.** During the applicable Royalty Term, Roche shall pay Poseida, in accordance with Article 9, on a per-Tier 1 Product or per-Optioned Tier 2 Product, as applicable, and country-by-country basis, and subject to Sections 8.9.1, 8.9.2(b), 8.9.3, and 8.9.4, a non-creditable, non-refundable royalty on worldwide Annual Net Sales of such Tier 1 Product or Optioned Tier 2 Product, as applicable, as follows:

Worldwide Annual Net Sales Thresholds	Tier 1 Programs royalty rates applicable to such portion	Tier 2 Programs with Option exercise at Completion of Phase I DE+ (pursuant to Section 3.2.3) royalty rates applicable to such portion	Tier 2 Programs with Option exercise at ED-Go (pursuant to Section 3.2.1) royalty rates applicable to such portion
Portion of worldwide Annual Net Sales [***]	[***]%*	[***]%	[***]%
Portion of worldwide Annual Net Sales [***]	[***]%*	[***]%	[***]%
Portion of worldwide Annual Net Sales [***]	[***]%*	[***]%	[***]%

*The royalty rates for a Tier 1 Product that is subject to the Tier 1 Process Development Plan are subject to permanent adjustment (on a product-by-product basis) [***]

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[***].

8.8.2 **Collaboration Products.** During the applicable Royalty Term, Roche shall pay Poseida, in accordance with Article 9, on a Collaboration Product-by-Collaboration Product and country-by-country basis, and subject to Sections 8.9.1, 8.9.2(b), 8.9.3, and 8.9.4, a non-creditable, non-refundable royalty on worldwide Annual Net Sales of such Collaboration Products, as follows:

Worldwide Annual Net Sales Thresholds	Program Transition at Completion of Phase I DE+ (pursuant to Section 3.4.4) royalty rates applicable to such portion	Program Transition at ED-Go (pursuant to Section 3.4.6) royalty rates applicable to such portion
Portion of worldwide Annual Net Sales [***]	[***]%*	[***]%**
Portion of worldwide Annual Net Sales [***]	[***]%*	[***]%**
Portion of worldwide Annual Net Sales [***]	[***]%*	[***]%**

* If the applicable Collaboration Product uses [***], then the royalty rates above for such Collaboration Product will be [***].

** If the applicable Collaboration Product uses [***], then the royalty rates above for such Collaboration Product will be [***].

8.8.3 **Licensed Products.**

(a) **Autologous Licensed Products; Allogeneic Licensed Products.** During the applicable Royalty Term, Roche shall pay Poseida, in accordance with Article 9, on a per- Royalty Eligible Autologous Licensed Product or per-Royalty Eligible Allogeneic Licensed Product, as applicable, and country-by-country basis, and subject to Sections 8.9.2(b) and 8.9.4, a non-creditable, non-refundable, a royalty of [***] on worldwide Annual Net Sales of such Royalty Eligible Autologous Licensed Product or Royalty Eligible Allogeneic Licensed Product, as applicable. On a country-by-country basis, an Autologous Licensed Product is a “**Royalty Eligible Autologous Licensed Product**” or an Allogeneic Licensed Product is a “**Royalty Eligible Allogeneic Licensed Product**”, as applicable, if either (i) [***] or (ii) [***].

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(b) **iPSC-Derived Licensed Products.** During the applicable Royalty Term, Roche shall pay Poseida, in accordance with Article 9, on an iPSC-Derived Licensed Product-by- iPSC-Derived Licensed Product and country-by-country basis, and subject to Section 8.9.2(b) and 8.9.4, a non-creditable, non-refundable royalty of [***] on worldwide Annual Net Sales of such iPSC-Derived Licensed Product. [***].

8.8.4 **Royalty Term.** “**Royalty Term**” means:

(a) **Therapeutic Products.** With respect to a Therapeutic Product, on a Therapeutic Product-by-Therapeutic Product and country-by-country basis, the period of time commencing upon the First Commercial Sale of such Therapeutic Product in such country, and expiring on a country-by-country basis upon the later of: (i) the expiration of the last-to-expire Valid Product Claim for such Therapeutic Product in such country and (ii) the [***] of the First Commercial Sale of such Therapeutic Product in such country.

(b) **Royalty Eligible Autologous Licensed Products; Royalty Eligible Allogeneic Licensed Products.** With respect to a Royalty Eligible Autologous Licensed Product or a Royalty Eligible Allogeneic Licensed Product, on a per-Royalty Eligible Autologous Licensed Product or per-Royalty Eligible Allogeneic Licensed Product and country-by-country basis, the period of time commencing upon the First Commercial Sale of such Royalty Eligible Autologous Licensed Product or Royalty Eligible Allogeneic Licensed Product, as applicable, in such country and expiring on a country-by-country basis upon the later of: (i) expiration of the last-to-expire Valid Product Claim for such Royalty Eligible Autologous Licensed Product or Royalty Eligible Allogeneic Licensed Product in such country and (ii) the [***] of the First Commercial Sale of such Licensed Product in such country.

(c) **iPSC-Derived Licensed Products.** With respect to an iPSC-Derived Licensed Product, on an iPSC-Derived Licensed Product-by-iPSC-Derived Licensed Product and country-by-country basis, the period of time commencing upon the First Commercial Sale of such iPSC-Derived Licensed Product in such country and expiring on a country-by-country basis upon the expiration of the last-to-expire Valid Product Claim for such iPSC-Derived Licensed Product in such country.

8.8.5 **Rights Following Expiration of Royalty Term.** Upon expiration of the Royalty Term with respect to a Therapeutic Product or Licensed Product, as applicable, in a country, the applicable licenses in Sections 6.1.1 (for a Tier 1 Product), 6.2.1 (for an Optioned Tier 2 Product), 6.3.1(b) (for a Collaboration Product) and 6.6.4(b) (for a Licensed Product) shall be fully paid-up, perpetual, and irrevocable with respect to such Therapeutic Product or Licensed Product in that country.

8.8.6 **Single Royalty.** No more than one stream of royalty payments shall be due under this Section 8.8 with respect to sales of any one particular Therapeutic Product or Licensed Product. For the avoidance of doubt, multiple royalties shall not be payable because the sale of a particular Therapeutic Product or Licensed Product is Covered by more than one (1) Valid Product Claim in the country in which such Therapeutic Product or Licensed Product is sold.

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8.9 **Payment Offsets and Reductions.**

8.9.1 **Royalty Reduction for No Valid Product Claim.** If in any Calendar Quarter during the Royalty Term of a Therapeutic Product, the sale of such Therapeutic Product [***], all royalty payments pursuant to Section 8.8.1 or 8.8.2 that would otherwise be payable hereunder for such Therapeutic Product in such country shall be reduced by [***].(subject to Section 8.9.4) for the remainder of such Royalty Term.

- 8.9.2 [***].

- 8.9.3 [***].

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[***].

8.9.4 Cumulative Offsets and Reductions. The reductions and offsets to payments set forth in this Section 8.9, if applicable, shall be cumulative, [***] for such Therapeutic Product or Licensed Product in the applicable Calendar Quarter during the applicable Royalty Term under, in the case of a Therapeutic Product, the rates set forth in the tables in Section 8.8.1 (as adjusted per that Section for a particular Tier 1 Program) or Section 8.8.2 (as adjusted per that Section for a particular Collaboration Product), as applicable, and in the case of a Licensed Product, the rates set forth in Section 8.8.3(a) or 8.8.3(b), as applicable. [***].

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8.10 [***].

ARTICLE 9
Payment Terms; Reports; Audits

9.1 Notice of Milestone Achievement; Timing of Milestone Payment.

9.1.1 **Development and Regulatory Milestones.** With respect to each of the milestone events set forth in Section 8.6.1 and 8.6.2, the Party that achieved such milestone event and with respect to each of the milestone events set forth in Section 8.6.3, Roche shall inform the other Party or Poseida, as applicable, within [***] following the achievement of such event. Roche shall pay Poseida the respective milestone payment payable pursuant to Section 8.6 for achievement of such milestone event within [***] of receipt of an undisputed invoice from Poseida with respect thereto after achievement of such milestone event.

9.1.2 **Net Sales Milestones.** With respect to each of the milestone events set forth in Section 8.7, Roche shall inform Poseida within [***] following the end of the Calendar Quarter in which the achievement of such event occurred, and Roche shall pay Poseida the respective milestone payment payable pursuant to Sections 8.7 for achievement of such milestone event within [***] of receipt of an undisputed invoice from Poseida with respect thereto after achievement of such milestone event.

9.2 **Timing of Royalty Payment.** All royalty payments due under Section 8.8 shall be made within [***] of the end of each Calendar Quarter in which the sale was made.

9.3 **Royalty Report.** For each Calendar Quarter for which Roche has an obligation to make royalty payments pursuant to Section 8.8, within [***] after the end of such Calendar Quarter, [***]. Each royalty payment made by Roche pursuant to Section 8.8 shall be accompanied by a report that specifies, on a per-Therapeutic Product or per-Licensed Product basis, for such Calendar Quarter the following information:

(a) total Sales and Net Sales of the applicable Therapeutic Products and Licensed Products;

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applicable; (c) any adjustments made pursuant to this Agreement, including Sections 8.9.1, (b) the royalty rate(s) applied pursuant to Sections 8.8.1, 8.8.2 or 8.8.3, as

8.9.2(b), 8.9.3, and 8.9.4; and

(d) the total royalties due to Poseida.

9.4 **Invoicing.** Poseida shall send invoices under this Agreement to Roche via e-mail to the [***] (and to [***] may request) or to such other address as Roche may designate from time to time. Roche shall send invoices under this Agreement to Poseida at its address set forth in Section 17.2 or to such other address as Poseida may designate from time to time.

9.5 **Mode of Payment.** All payments hereunder shall (unless otherwise specifically designated) be non-creditable and non-refundable; and all payments to Poseida hereunder shall be made in immediately available funds to the account listed below (or such other account as Poseida shall designate before such payment is due):

[***]

All payments to Roche hereunder shall be made in immediately available funds to the account designated by Roche before such payment is due.

9.6 **Currency of Payments.** All amounts set forth herein (including all payments) are in US Dollars, unless otherwise expressly provided in this Agreement. Net Sales outside of the US shall be first determined in the currency in which they are earned and shall then be converted into an amount in US Dollars as follows: (a) with respect to Sales by or on behalf of Roche or an Affiliate pursuant to Section 1.146.1, using Roche's or such Affiliate's customary and usual conversion procedures, consistently applied and (b) with respect to Sales by or on behalf of a given Sublicensee pursuant to Section 1.146.2, using the conversion procedures applicable to payments by such Sublicensee to Roche for such sales.

9.7 **Blocked Currency.** If, at any time, legal restrictions prevent Roche (or an Affiliate or Sublicensee) from remitting part or all of payments when due with respect to any country worldwide where Therapeutic Products or Licensed Products are sold, Roche shall continue to provide the reports set forth in Section 9.2 for such payments, and such payments shall continue to accrue in such country, but Roche shall not be obligated to make such payments, and, for clarity, Section 9.12.5 shall not apply to such payments, until such time as payment may be made through reasonable, lawful means or methods that may be available, as Roche shall reasonably determine.

9.8 **Withholding Taxes.** Poseida shall pay all sales, turnover, income, revenue, value added, and other taxes levied on account of any payments accruing or made to Poseida under this

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Agreement. If provision is made in law or regulation of any country for withholding of taxes of any type, levies or other charges with respect to any royalty or other amounts payable under this Agreement to Poseida and such withholdings cannot be reduced or eliminated under an applicable tax treaty, then [***]. Each Party agrees to reasonably assist the other Party in claiming exemption from such deductions or withholdings under double taxation or similar agreement or treaty from time to time in force and in minimizing the amount required to be so withheld or deducted. Roche shall use commercially reasonable efforts to inform Poseida of any forms, certificates or other items necessary to reduce or eliminate any such withholding or similar taxes and provide Poseida a reasonable opportunity to provide such forms, certificate or other items. Notwithstanding the foregoing, the Parties acknowledge and agree that if Roche (or its assignee pursuant to Section 17.3) is required by applicable law to withhold taxes in respect of any amount payable under this Agreement, and if such withholding obligation arises or is increased solely as a result of any action by Roche or its Affiliates after the Execution Date, including, without limitation, any assignment of this Agreement by Roche as permitted under Section 17.3, a Change in Control of Roche, a change in tax residency of Roche, a change in the entity making payment under this Agreement, a failure of Roche to comply with applicable laws, or payments arise or are deemed to arise through a branch of Roche (each, a “**Withholding Tax Action**”), then, notwithstanding anything to the contrary herein, any such amount payable to Poseida under this Agreement shall be increased to take into account such increased withholding taxes as may be necessary so that, after making all required withholdings, Poseida (or its assignee pursuant to Section 17.3) receives an amount equal to the sum it would have received had no such Withholding Tax Action occurred.

9.9 **German Withholding Tax.** The Parties acknowledge that payments to Poseida with respect to the rights in Germany granted to Roche under this Agreement may be subject to (i) German income tax pursuant to sec. 49 para. 1 German Income Tax Act and (ii) withholding tax pursuant to sec. 50a para. 1 German Income Tax Act (the “**German WHT Requirement**”). Without limiting anything in this Article 9, the following shall apply:

(a) Poseida shall provide Roche with all information relevant to assess the applicability of and the tax assessment basis for the German WHT Requirement;

(b) Reasonably taking into account any comments and information received from Poseida, Roche shall use [***] to determine (i) whether the German WHT Requirement is applicable on the licenses granted to Roche under this Agreement and (ii) the amount to be withheld and remitted to the competent German tax authority (including the allocation to and calculation of the assessment basis for the withholding);

(c) Based on the determination made pursuant to Section 9.9(b), Roche shall remit the withheld amount to the competent German tax authority in due course. With regards to Roche’s payment obligations under this Agreement, any amount paid to the German tax authority pursuant to the preceding sentence shall be deemed as payment to Poseida;

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(d) Roche shall cooperate with Poseida to apply for and obtain a valid exemption certificate (*Freistellungsbescheinigung*) issued by a competent German tax authority confirming that Roche is not required to withhold from payments to Poseida pursuant to the German WHT Requirement;

(e) As soon as Roche has received a valid exemption certificate (*Freistellungsbescheinigung*) issued by a competent German tax authority (upon the application of Poseida) confirming that Roche is not required to make a withholding pursuant to the German WHT Requirement, Roche shall not be allowed to make any deductions from any payments pursuant to this Section 9.9 for the time period specified in the exemption certificate; and

(f) If Roche receives a request by a competent German tax authority to make a payment based on or in connection with the German WHT Requirement, Poseida shall indemnify Roche from such payment obligation without undue delay. Roche shall be allowed to offset its indemnification claim pursuant to the preceding sentence against payments due under this Agreement to Poseida.

9.10 **Indirect Taxes.** Notwithstanding anything to the contrary in this Agreement, all amounts stated herein are exclusive of any transfer, documentary, sales, use, stamp, registration, value-added, goods and services tax or other similar tax (each an “**Indirect Tax**”). The Parties shall cooperate to minimize any such applicable Indirect Taxes. To the extent Indirect Taxes are applicable with respect to the transactions, payments or the related transfer of rights or other property pursuant to the terms of this Agreement, the [***] any such Indirect Taxes imposed. [***].

9.11 **Foreign Derived Intangible Income.** Roche shall use commercially reasonable efforts to provide, and to cause its Affiliates, subcontractors, Sublicensees, customers, and applicable Third Parties to provide, any information and documentation reasonably requested by Poseida to obtain the benefits of Section 250 of the Internal Revenue Code of 1986, as amended and the applicable Treasury Regulations.

9.12 **Records; Inspection.**

9.12.1 **Records.** Roche agrees to keep, for [***] from the year of creation, records of all sales of Therapeutic Products and Licensed Products for each reporting period in which royalty payments are due, showing sales of Therapeutic Products and Licensed Products for Roche and applicable deductions in sufficient detail to enable the royalty reports provided under Section 9.2 to be verified.

9.12.2 **Audits.** Poseida shall have the right to request that reports provided under Section 9.2 be verified by a CPA Firm. Such right to request a verified report shall (a) be limited to the [***] period during which Roche is required to maintain the same, (b) not be exercised more than [***] in any Calendar Year, and (c) not be exercised more than [***] with respect to records covering any specific period of time. Subject to Section 9.12.3, Roche shall, upon reasonable advance notice and at a mutually agreeable time during its regular business hours, make its records

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available for inspection by such CPA Firm at such place or places where such records are customarily kept, solely to verify the accuracy of such applicable reports and related payments due under this Agreement. The CPA Firm shall only state factual findings in the audit reports. The CPA Firm shall share all draft audit reports with Roche before the draft audit report is shared with Poseida and before the final document is issued. The final audit report shall be shared with Roche at the same time that it is shared with Poseida.

9.12.3 **Confidentiality.** Prior to any audit under Section 9.12.2, the CPA Firm shall enter into a written confidentiality agreement with Roche that (a) limits the CPA Firm's use of the Roche's records to the verification purpose described in Section 9.12.2; (b) limits the information that the CPA Firm may disclose to Poseida to the results of such audit in at least as much detail as the royalty reports provided in Section 9.3 and a high level summary of the results of the audit, *provided*, such high level summary does not contain Roche's sensitive confidential information (as defined in the written confidentiality agreement between Roche and the applicable CPA Firm); and (c) prohibits the disclosure of any information contained in such records to any Third Party for any purpose. The Parties agree that all information subject to review under Section 9.12.2 or provided by the CPA Firm to Poseida is Roche's Confidential Information, and Poseida shall not use any such information for any purpose that is not germane to Section 9.12.2.

9.12.4 **Underpayment; Overpayment.** After reviewing the CPA Firm's audit report, Roche shall promptly pay any uncontested, understated amounts due to Poseida. Any overpayment made by Roche shall be promptly refunded or fully creditable against amounts payable in subsequent payment periods, at Roche's election. Any audit under Section 9.12.2 shall be [***]; provided, however, [***] shall reimburse reasonable audit fees for a given audit if the results of such audit reveal that [***] underpaid [***] with respect to royalty payments by [***] or more for the audited period.

9.12.5 **Late Payments.** If any payment due to either Party under this Agreement is not paid when due, then such paying Party shall pay interest thereon (before and after any judgment) at an annual rate (but with interest accruing on a daily basis) of [***] above EURIBOR (or such other interbank rate acceptable to both Parties), such interest to run from the date on which payment of such sum became due until payment thereof in full together with such interest.

ARTICLE 10

Confidentiality; Data Privacy & Security

10.1 **Definition.** "Confidential Information" of a Party means the confidential or proprietary information (of whatever kind and in whatever form or medium, including copies thereof) disclosed in any form (written, oral, electronic, photographic or otherwise) by or on behalf of such Party ("Disclosing Party") to, or otherwise accessed by, the other Party (the "Receiving Party") in connection with this Agreement, whether prior to or during the Term, including Know-How or other information (whether or not patentable) regarding such Party's research, development plans, clinical trial designs, preclinical and clinical data, technology, products, business information or objectives, reports and audits under this Agreement and other information of the type that is customarily considered to be confidential or proprietary information by entities engaged in activities that are substantially similar to the activities being engaged in by the Parties pursuant to

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this Agreement, including all proprietary materials as well as data and information associated therewith. [***].

10.2 **Exclusions Regarding Confidential Information.** Notwithstanding anything in this Article 10 to the contrary, Confidential Information of the Disclosing Party shall not include information that the Receiving Party can demonstrate with written records:

10.2.1 was already known to the Receiving Party, other than under an obligation of confidentiality, at the time of receipt by the Receiving Party as shown by the Receiving Party's files and records immediately prior to the time of disclosure; *provided* that the foregoing exception shall not apply with respect to Confidential Information described in the penultimate sentence of Section 10.1 as being Confidential Information of the Party that received such information;

10.2.2 except with respect to any Personal Data (as defined below), was generally available to the public or otherwise part of the public domain at the time of its receipt by the other Receiving Party;

10.2.3 except with respect to any Personal Data (as defined below), became generally available to the public or otherwise part of the public domain after its receipt by the Receiving Party other than through any act or omission of such other Receiving Party in breach of this Agreement;

10.2.4 was received by the Receiving Party without an obligation of confidentiality and non-use from a Third Party, which Third Party the Receiving Party believed to have no obligation of confidentiality and non-use regarding such information;

10.2.5 was independently developed by or for the Receiving Party without use of or reference to the Confidential Information of the Disclosing Party as shown by the Receiving Party's files and records immediately prior to the time of disclosure; *provided* that the foregoing exceptions shall not apply with respect to Confidential Information described in the penultimate sentence of Section 10.1; or

10.2.6 was released from the restrictions set forth in this Agreement by express prior written consent of the Disclosing Party.

10.3 **Non-Use and Non-Disclosure of Confidential Information.** During the Term, and for a period of [***] thereafter, a Party shall (a) except to the extent expressly permitted by this Agreement or otherwise agreed to in writing, keep confidential and not disclose to any Third Party or use for any purpose any Confidential Information of the other Party; and (b) take reasonable

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precautions to protect the Confidential Information of the other Party from unauthorized use or disclosure (including all precautions a Party employs with respect to its own confidential information of a similar nature and taking reasonable precautions designed to assure that no unauthorized use or disclosure is made by others to whom access to the Confidential Information of the Party is granted); *provided*, that any Confidential Information that constitutes a trade secret and that has been specifically identified as a trade secret in writing by the Disclosing Party to the Receiving Party shall continue to be subject to the obligations of non-use and non-disclosure until such Confidential Information is no longer a trade secret. Each Party shall ensure that its personnel who have access to Confidential Information have agreed to appropriate confidentiality obligations.

10.4 **Authorized Disclosures of Confidential Information.** A Receiving Party may use and disclose the Confidential Information of the Disclosing Party as follows:

10.4.1 if required by applicable laws, rules or regulations (including rules of any applicable Exchange), provided that the Receiving Party (a) if permitted by applicable laws, rules or regulations, use [***] to inform the Disclosing Party prior to making any such disclosures and reasonably cooperate with the Disclosing Party in seeking a protective order or other appropriate remedy (including redaction) and (b) whenever possible, request confidential treatment of such information;

10.4.2 as reasonably necessary to exercise its rights or fulfil its obligations under this Agreement or exercise its ownership rights in Joint IP;

10.4.3 to the extent such use and disclosure is reasonably required in the Prosecution and Maintenance of a Patent claiming a Program Invention or within Poseida Technology Improvements or Roche Technology Improvements in accordance with this Agreement;

10.4.4 as reasonably necessary to obtain or maintain any Regulatory Approval, including to conduct preclinical studies and clinical trials and for pricing approvals, for any Therapeutic Product or Licensed Product, provided, that, the Receiving Party shall take all reasonable steps to limit disclosure of the Confidential Information outside such Regulatory Authority and to otherwise maintain the confidentiality of the Confidential Information; or

10.4.5 to the extent necessary, to its board members, permitted sublicensees, collaborators, vendors, consultants, agents, attorneys, accountants, contractors and clinicians under written agreements of confidentiality at least as restrictive on those set forth in this Agreement and who have a need to know such information in connection with the Receiving Party performing its obligations, exercising its licenses or other rights under this Agreement or as required under applicable laws, rules or regulations (including rules of any applicable Exchange). Further, the Receiving Party may disclose Confidential Information to its board members, existing or bona fide potential acquirers, merger partners, permitted collaborators, sublicensees and sources of financing or to professional advisors (e.g., attorneys, accountants and prospective investment bankers) involved in such activities, for the limited purpose of evaluating such transaction, collaboration or sublicense and under appropriate written conditions of confidentiality, provided that such disclosures are limited to only such information that is reasonably necessary for such purpose.

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Each Receiving Party shall remain liable for breach for this Agreement by the permitted recipients in this Section 10.4.5 as if such breach were by the Receiving Party itself.

10.5 **Information Security Incident.**

10.5.1 **Notification.** A Party shall provide to the other Party written notice within [***] of such Party's confirmation of an Information Security Incident with respect to the other Party's Confidential Information. Such notice shall describe in reasonable detail the Information Security Incident, including the other Party's Confidential Information impacted, the extent of such impact and any corrective action taken or to be taken by such Party. In addition, if a Party reasonably suspects (even if it has not confirmed) that an actual or attempted Information Security Incident has occurred with respect to the other Party's Confidential Information, then the Party shall promptly notify the other Party of such suspected actual or suspected Information Security Incident.

10.5.2 **Non-Disclosure.** Except to the extent required by applicable laws, rules or regulations (including rules of any applicable Exchange), neither Party shall disclose any information related to an actual or suspected Information Security Incident of the other Party's Confidential Information to any Third Party without the other Party's prior written consent.

10.6 **Termination of Prior Agreements.** As of the Effective Date, as between the Parties, this Agreement supersedes the Non-Disclosure Agreement between Poseida and Roche, dated [***] ("**Prior NDA**"), and the Parties agree that disclosures made prior to the Effective Date pursuant to the Prior NDA shall be subject to the provisions of this Article 10 as the Confidential Information of the Party that disclosed such information pursuant to the Prior NDA and each Party shall remain liable for its breach, if any, of the Prior NDA that occurred prior to the Effective Date.

10.7 **No License.** Subject to the penultimate sentence of Section 10.1, as between the Parties, Confidential Information disclosed hereunder shall remain the property of the Disclosing Party. Disclosure of Confidential Information to the other Party shall not constitute any grant, option or license to the other Party, beyond those licenses expressly granted under Article 6, under any Patent, Know-How, trade secret or other rights now or hereinafter held by the Disclosing Party.

10.8 [***].

10.9 **Data Privacy.** The Parties acknowledge that Poseida may collect and otherwise process data that identifies or could be used to identify an individual person or device (together with any information that constitutes "personal information," "personal data" or any similar term under

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applicable law, “**Personal Data**”) regarding patients or other individuals in connection with the clinical trials contemplated to be performed by Poseida, or a Third Party acting on Poseida’s behalf, under this Agreement. Notwithstanding anything to the contrary in this Agreement, to the extent data related to such clinical trials are to be provided to Roche under this Agreement, any data contained therein regarding patients or other clinical trial participants shall be provided solely in de-identified form. The Parties shall enter into any necessary agreements with respect to any transfer of Personal Data between the Parties to comply with applicable privacy laws.

ARTICLE 11

Publicity; Publications; Use of Name

11.1 **Publicity.** Following the Execution Date, Poseida may issue a press release concerning the execution of this Agreement in the form attached hereto as Exhibit 11.1.

11.2 **Subsequent Releases.** Subject to Section 11.4, (a) Poseida may not issue any other press releases or other public statements or announcement concerning this Agreement, the subject matter hereof, or the research, development, manufacturing or commercial results of Therapeutic Products, Licensed Products, Tier 1 Programs, Tier 2 Programs, or Collaboration Programs hereunder (a “**Release**”) without Roche’s prior written consent; and (b) Roche may not issue a Release without Poseida’s prior written consent if it includes reference to Poseida by name, in each case (a) and (b), subject to Sections 11.3 and 11.4, such consents to not be unreasonably withheld, conditioned, or delayed (provided that inclusion of the financial terms set forth herein in such Release shall be an appropriate reason to withhold such consent). Each Party shall provide such consent (or explain why it is withholding consent) within [\[***\] of receipt of a proposed Release from the other Party](#).

11.3 **Approved Releases.** If a Release requires consent pursuant to Section 11.2, once consent has been given, both Parties may make subsequent public disclosure of the contents of such Release (or the Release issued pursuant to Section 11.1) without the further approval of the Party whose consent was required; provided that such information remains accurate as of such time and is not presented with any new data or information or conclusions and/or in a form or manner that materially alters the subject matter therein. Notwithstanding the foregoing, any press release by or on behalf of a Party that constitutes a Release shall be subject to the terms of Section 11.2 whether or not such Release includes the content of a previously approved Release.

11.4 **Releases Required by Law or Regulation.** Each Party may issue any Release it is required to issue by applicable laws, rules or regulations (including rules of any applicable Exchange); provided that if applicable laws, rules or regulations require the issuing Party to disclose any of the other Party’s Confidential Information in such Release, it (a) to the extent permitted by applicable laws, rules or regulations, uses [***] to inform the other Party prior to making any such Release to permit such other Party the opportunity to seek to obtain a protective order or other confidential treatment preventing or limiting the required disclosure, and (b) discloses only such Confidential Information of the other Party that it is advised by counsel is legally required to be disclosed in such Release. To the extent such other Party seeks to obtain a protective order or other confidential treatment to prevent or limit the required disclosure, the issuing Party shall reasonably assist such other Party (unless prohibited by applicable law, rules or

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regulations), but shall not be required to delay such Release beyond the requirements of the applicable laws, rules or regulations (including rules of any applicable Exchange).

11.5 **Filing of Agreement.** With respect to complying with the disclosure requirements of an Exchange, in connection with any required filings of this Agreement with such Exchange, the filing Party shall, at the request of the other Party, seek confidential treatment for portions of this Agreement from such Exchange and shall provide such other Party with the opportunity, for no less than [***] (before the date of the proposed filing), to review and comment on any such proposed filing, and shall thereafter provide reasonable advance notice and opportunity for comment on any subsequent changes to such filing. A Party shall reasonably and in good faith take into account the comments of the other Party and incorporate such comments in good faith where such comments are consistent with Exchange requirements.

11.6 **Publications.** Each Party shall have the right to publish information arising from this Agreement in scientific publications and presentations in accordance with this Section 11.6. With respect to any such paper or presentation (including posters, slides, abstracts, manuscripts, marketing materials and written descriptions of oral presentations) proposed for publication by a Party that includes (a) [***] of the non-publishing Party or (b) [***], the publishing Party shall submit to the non-publishing Party the proposed publication or presentation at least [***] for abstracts of manuscripts, posters, or presentations) prior to the date of submission for publication or the date of presentation, whichever is earlier, of any such submitted materials. The non-publishing Party shall review such submitted materials and respond to the publishing Party as soon as reasonably possible, but in any case within [***] for abstracts of manuscripts, posters, or presentations) of receipt thereof. With respect to such paper or presentation that includes (a) above, at the request of the non-publishing Party, the publishing Party shall: (i) delete from such proposed publication or presentation any Confidential Information of the non-publishing Party; provided that neither Party shall be required to delete Confidential Information that is the Confidential Information of both Parties, from such proposed publication or presentation, subject to compliance with (ii) below; and (ii) delay the date of such submission for publication or the date of such presentation for a period of time sufficiently long (but in no event longer than [***]) to permit the non-publishing Party to seek appropriate patent protection of its rights in information disclosed therein in accordance with Article 12.

Once a publication has been approved by the non-publishing Party, each Party may make subsequent public disclosure of the contents of such publication without the further approval of the other Party; provided that such information remains accurate as of such time and is not presented with any new data or information or conclusions and/or in a form or manner that materially alters the subject matter therein. [***]. Each Party shall adhere to standard academic practice regarding authorship of scientific publications and recognition of the contribution of the other Party for any publication or presentation that includes information arising from this Agreement.

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11.7 **No Right to Use Names.** Except as expressly provided herein and to the extent that such use is not inconsistent with prior public disclosures or presentations, no right, express or implied, is granted by the Agreement to use in any manner the name of a Party (*i.e.*, “Poseida” or “Roche”, as applicable), or any other trade name, symbol, logo or Trademark of the other Party in connection with the performance of this Agreement, except to the extent required by applicable law. Notwithstanding the foregoing, Poseida shall be permitted to include the name and/or Roche- approved version of Roche’s corporate logo in connection with the description of this Agreement

(a) on Poseida’s corporate website and investor presentations, in each case solely for the purpose of identifying Roche as a collaborator and subject to Roche’s review and approval (not to be unreasonably withheld or delayed) that Poseida’s proposed use complies with Roche’s written branding guidelines with respect to use of such name, trademark and/or logo and such use only contains accurate and non-misleading factual statements regarding the Parties’ relationship and (b) on social media, subject to Roche’s review and approval (not to be unreasonably withheld or delayed) of the social media platform and content during the [\[***\] period immediately following the Effective Date to announce this Agreement by posting a link to the press release on Exhibit](#)

[11.1. Roche may reasonably request from time to time samples of the documents or other materials, or screen shots of the websites, containing Poseida’s use of Roche’s name, trademarks and/or logo to ensure compliance with Roche’s written branding guidelines and the terms of this Section 11.7, and Poseida shall promptly comply with such reasonable requests.](#)

ARTICLE 12 Intellectual Property

12.1 **Disclosure.** During the Term, each Party shall promptly disclose to the other Party any Program Inventions made by such Party, its Affiliates or its/their sublicensee after the Effective Date that are within the assignment obligations to the other Party under Article 12 or within the Joint IP.

12.2 **Ownership.** Each Party will continue to own any Patents and Know-How that it owned prior to the Effective Date or that it discovers, conceives or otherwise obtains independently of this Agreement. Subject to the licenses set forth in Article 6: (a) [***], (b) [***], (c) [***], and (d) [***]. The determination of whether the inventions described in [***] are invented by or on behalf of a Party for purposes of allocating proprietary rights therein shall, for purposes of this Agreement, be made in accordance with the US patent laws. Subject to the licenses and obligations

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set forth in Article 6 and Article 7, each Party has the right to practice, license, sublicense, assign, transfer and otherwise exploit such Party's interest in the Joint IP (including Patents therein) for any and all purposes on a worldwide basis without restriction, and without the consent of and without a duty of accounting to the other Party. Each Party will grant and hereby does grant all permissions, consents and waivers with respect to, and all licenses under, such Party's interest in the Joint IP, throughout the world, necessary to provide the other Party with the foregoing rights.

12.3 **Assignment and Cooperation.** The assignments necessary to accomplish the ownership provisions set forth in Section 12.2 are hereby made by each Party to the other Party, and each Party shall execute such further documentation as may be necessary or appropriate, and provide reasonable assistance and cooperation to implement the provisions of Section 12.2. Without limiting the foregoing, each Party agrees to execute such documents, render such assistance, and take such other action as the other Party may reasonably request, to apply for, register, record, perfect, confirm, and protect the other Party's rights in such Know-How and intellectual property rights (including Patents) therein to effect the intent of Section 12.2. Each Party shall require, to the extent legally possible under relevant national or local laws, all of its employees, Affiliates, Authorized Subcontractors and Sublicensees to assign (or otherwise convey rights) to such Party its right, title and interests in any Patents and Know-How discovered or conceived by such employee, Affiliate, Authorized Subcontractor or Sublicensee and to cooperate with such Party in connection with obtaining Patent protection therefor.

12.4 **Prosecution and Maintenance.**

12.4.1 **Poseida Control.**

(a) **General.** As between the Parties, Poseida shall, [***], have the: (a) [***],
 (b) first right, but not the obligation, to control and make decisions with respect to the Prosecution and Maintenance of [***] (the Patents in (b), "**Poseida Prosecuted Patents**"), and (c) sole right to control and make decisions with respect to Prosecution and Maintenance of [***].

(b) **Coordination of Poseida Prosecuted Patents, Product-Specific Patents, Joint Patents, and [***].** With respect to a [***], for which Poseida assumes Prosecution and Maintenance, Poseida shall provide Roche with any copies of material communications to and from any patent authority and drafts of substantive official correspondence with patent authorities with respect to such Patent sufficiently in advance (where reasonable) for Roche to comment, which comments Poseida shall consider in good faith.

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[***].

Roche shall have the right to request that Poseida [***]. In the event that Poseida does not agree to Roche's request, Roche shall have the right, [***], to [***].

(c) **Step-In Rights for Poseida Prosecuted Patents.** If Poseida decides not to Prosecute and Maintain any Poseida Prosecuted Patent (including if it decides not to file in one or more jurisdictions), Poseida shall notify Roche in writing at least [***] prior to any relevant deadline or filing or response date, and Roche shall thereupon have the right, but not the obligation, to assume the Prosecution and Maintenance (including the right to file in jurisdictions in which Poseida has decided not to file) of such Poseida Prosecuted Patent [***] subject to the remainder of this Section 12.4.1(c) and the Parties shall discuss in good faith regarding any action proposed to be taken by Roche. Following such discussion, if the Parties cannot agree upon a mutually acceptable strategy, [***]. If Roche assumes Prosecution and Maintenance of a Poseida Prosecuted Patent, then Roche shall provide Poseida with any copies of material communications to and from any patent authority and drafts of substantive official correspondence with patent authorities with respect to such Poseida Prosecuted Patent sufficiently in advance (where reasonable) for Poseida to comment, which comments Roche shall consider in good faith and reasonably incorporate.

12.4.2 Roche Control.

(a) **General.** As between the Parties, Roche shall, [***], have (a) the first right, but not obligation, to control and make decisions with respect to Prosecution and Maintenance of the (i) [***] (the Patents in (i) and

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(ii), the “**Roche Prosecuted Patents**”) and (b) sole right to control and make decisions with respect to Prosecution and Maintenance of all Patents within [***].

(b) **Coordination of Roche Prosecuted Patents.** With respect to any [***] for which Roche assumes Prosecution and Maintenance, Roche shall provide Poseida with any copies of material communications to and from any patent authority and drafts of substantive official correspondence with patent authorities with respect to such [***] sufficiently in advance (where reasonable) for Poseida to comment, which comments Roche shall consider in good faith and reasonably incorporate. [***].

(c) **Step-In Rights for Roche Prosecuted Patents.** If Roche decides not to Prosecute and Maintain any Roche Prosecuted Patent (including if it decides not to file in one or more jurisdictions), Roche shall notify Poseida in writing at least [***] prior to any relevant deadline or filing or response date, and Poseida shall thereupon have the right, but not the obligation, to assume the Prosecution and Maintenance (including the right to file in jurisdictions in which Roche has decided not to file) of such Roche Prosecuted Patent at [***], subject to the remainder of this Section 12.4.2(c) and the Parties shall discuss in good faith regarding any action proposed to be taken by Poseida. Following such discussion, if the Parties cannot agree upon a mutually acceptable strategy, [***]. If Poseida assumes Prosecution and Maintenance of a Roche Prosecuted Patent, then Poseida shall provide Roche with any copies of material communications to and from any patent authority and drafts of substantive official correspondence with patent authorities with respect to such Roche Prosecuted Patent sufficiently in advance (where reasonable) for Roche to comment, which comments Poseida shall consider in good faith and reasonably incorporate.

12.4.3 **Further Acts.** At the prosecuting Party’s request and expense, each Party will reasonably cooperate with and assist each other in the Prosecution and Maintenance of Patents claiming Program Inventions, including making scientists and scientific records reasonably available and using [***] to have documents signed as necessary in connection with such Prosecution and Maintenance.

12.5 **Unified Patent Court.** At any time prior to the end of the “transitional period” as such term is used in Article 83 of the Agreement on a Unified Patent Court between the participating Member States of the European Union, for a given relevant Roche Prosecuted Patent in the Member States of the European Union, Roche may request in writing that Poseida either (a) opt out from the exclusive competence of the Unified Patent Court or (b) if applicable, withdraw a previously-registered opt-out, and Poseida shall notify the United Patent Court Registry, pay any such registry fee and take such other action as may be necessary to effect the opt-out or opt-out withdrawal (“**Register**”). Poseida shall Register within [***] of receipt of Roche’s written request, or such other time parameters specified by Roche.

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12.6 **CREATE Act.** It is the intention of the Parties that this Agreement is a “joint research agreement” as that term is defined in 35 USC § 100(h), and as it applies to inventions as set forth in 35 USC § 102(c) (AIA) or 35 USC § 103(c) (pre-AIA) and may be used for the purpose of overcoming a rejection of a claimed invention within the Joint IP pursuant to the provisions of 35 USC § 102(c) or 35 USC § 103(c). In the event that either Party intends to overcome a rejection of any other claimed invention outside the Joint IP pursuant to the provisions of 35 USC § 102(c) or 35 USC § 103(c), such Party shall first obtain the prior written consent of the other Party.

12.7 **Patent Term Extension.** As between the Parties, with respect to each Therapeutic Product, Roche shall have the right to apply for patent term extensions (including supplementary protection certificates) worldwide for Roche Prosecuted Patents. Roche will promptly notify Poseida in writing of such patent term extension applications. [***]. If Roche, with respect to a Therapeutic Product, desires to apply for patent term extensions for a Poseida Prosecuted Patent, Roche will promptly notify Poseida in writing, in which case the Parties will discuss such proposal within [***] after such notice is received by Poseida; [***].

12.8 **Patent Listings.** Roche shall have the sole right to make all filings for Roche Prosecuted Patents with Regulatory Authorities worldwide relating to any Therapeutic Products, including as required or allowed under the national implementations of Article 10.1(a)(iii) of Directive 2001/EC/83 or other international equivalents. [***]. If Roche, with respect to a Therapeutic Product, desires to make any such filing for a Poseida Prosecuted Patent, Roche will promptly notify Poseida in writing, in which case the Parties will discuss such proposal within [***] after such notice is received by Poseida; provided that Roche will not have the right to make any such filing on such Patent without Poseida’s prior written consent.

12.9 **Product Trademarks.** Roche shall have the sole right to determine the Product Trademarks to be used with respect to the exploitation of the Therapeutic Products and Licensed Products on a worldwide basis. [***].

12.10 **Enforcement and Defense of IP; Defense of Third Party Infringement Claims.**

12.10.1 **Notice.** Each Party shall promptly notify the other Party upon learning of any (a) actual or suspected infringement or misappropriation by a Third Party of a [***], Poseida Prosecuted Patent or Roche Prosecuted Patent, in each case, arising from the exploitation of a product competitive with a Therapeutic Product (each in (a), an “**Infringement**”); or (b) claim

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by a Third Party of invalidity, unpatentability (including any Third Party-filed observations, reexaminations, inter partes reviews, and post grant reviews, as well as interferences and derivation proceedings, oppositions and other similar proceedings brought by a Third Party), unenforceability or non-infringement (or non-misappropriation) of a [***], [Poseida Prosecuted Patent or Roche Prosecuted Patent, in each case, that claim a Therapeutic Product \(or a component thereof\) or the composition of matter, method of use, or method of making the Therapeutic Product \(each in \(b\), a “Challenge”\)](#).

12.10.2 Enforcement of IP.

(a) **Control.** As between the Parties, (i) Roche shall have the first right, but not the obligation, to determine the appropriate course of action to enforce, defend or otherwise to abate the Infringement of a Roche Prosecuted Patent or [***], to take (or refrain from taking) appropriate action to enforce, to defend, to control any litigation or other enforcement or defense action, and to enter into, or permit, the settlement of any such litigation or other enforcement or defense action with respect to any such Infringement and (ii) Poseida shall have the first right, but not the obligation, to determine the appropriate course of action to enforce, defend or otherwise abate the Infringement of a Poseida Prosecuted Patent[***], to take (or refrain from taking) appropriate action to enforce, to defend, to control any litigation or other enforcement or defense action, and to enter into, or permit, the settlement of any such litigation or other enforcement or defense action with respect to any such Infringement. [***].

(b) **Step-In Rights.** If a Party with the first right to control any action described in Section 12.10.2(a) elects to not take any steps to abate such Infringement pursuant to Section 12.10.2(a) with respect to a Roche Prosecuted Patent, Poseida Prosecuted Patent, or [***], such Party with the first right shall notify the other Party within [***] after learning of the Infringement (or any shorter period of time that allows the other Party to have [***] to exercise its back-up right before a relevant court deadline), and the other Party shall then have the right (but not the obligation) to take action to enforce [***] the applicable Patents, against such Infringement, subject to the remainder of this Section 12.10.2(b) and the Parties shall discuss in good faith regarding any action proposed to be taken by the other Party. Following such discussion, if the Parties cannot agree upon a mutually acceptable strategy (including whether the other Party should have the right to take action to enforce such Patent), [***].

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(c) **Cooperation.** In each of Sections 12.10.2(a) and 12.10.2(b), the non-controlling Party shall cooperate with the Party controlling any such action (as may be reasonably requested by the controlling Party) at the controlling Party's expense, including, if necessary, by being joined as a party, and the Party controlling any such action shall keep the other Party regularly updated and informed with respect to any such action, including providing copies of material documents received or filed in connection with any such action.

(d) **Settlement.** The Party controlling any action described in Section 12.10.2(a) and 12.10.2(b) in connection with a Roche Prosecuted Patent, Poseida Prosecuted Patent or [***] shall not settle or consent to an adverse judgment (including any judgment that limits the scope, validity or enforcement of such Patent) without the express written consent of the non-controlling Party (such consent not to be unreasonably withheld), unless such settlement or judgment does not (i) impose any financial obligation upon the non-controlling Party or (ii) limit the scope of or invalidate any such Patent.

(e) **Damages.** Any recovery realized as a result of any action described in Section 12.10.2(a) or 12.10.2(b) (whether by way of settlement or otherwise) shall be first, allocated to reimburse the Parties for their costs and expenses in making such recovery (which amounts shall be allocated pro rata if insufficient to cover the totality of such expenses), and any remainder after such reimbursement is made shall be allocated [***].

12.11 Defense of Challenges.

12.11.1 **Control.** Poseida shall, [***], have the first right, but not obligation, to defend any Challenge of the Poseida Prosecuted Patents using outside counsel reasonably agreeable to both Parties. At Poseida's reasonable request and expense, Roche shall reasonably cooperate with Poseida in connection with any defense by Poseida in this Section 12.11, including, if necessary, by being joined as a party. Roche shall, [***], have the first right, but not obligation, to defend any Challenge of the Roche Prosecuted Patents and [***]. At Roche's reasonable request and expense, Poseida shall reasonably cooperate with Roche in connection with any defense by Roche in this Section 12.11, including, if necessary, by being joined as a party.

12.11.2 **Step-In Rights.** If the Party with a first right to defend a Challenge pursuant to Section 12.10.1 elects not to defend any Challenge, then such Party electing not to defend shall notify the other Party within [***] after learning of the Challenge (or any shorter period of time that allows the other Party to have [***] to exercise its back-

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up right in this Section 12.11.2 before a relevant court deadline), and the other Party shall then have the right (but not the obligation) to defend the Challenge [***] using outside counsel reasonably agreeable to both Parties. At the controlling Party's reasonable request and expense, the non-controlling Party shall reasonably cooperate with the controlling Party in connection with any defense of a Challenge described in this Section 12.11.2, including, if necessary, by being joined as a party. Notwithstanding anything to the contrary in this Section 12.11.2, (a) [***]; and (b) if Roche proposes any action with respect to a Poseida Prosecuted Patent, the Parties shall discuss in good faith regarding any such action. Following such discussion, if the Parties cannot agree upon a mutually acceptable strategy (including whether to take action to defend such Patent), Poseida shall have the final decision-making authority with respect to any such Poseida Prosecuted Patent. With respect to any defense of a Challenge pursuant to this Section 12.11.2, the Party controlling any such action shall keep the other Party updated with respect to any such action, including, at the other Party's request, providing copies of material documents received or filed in connection with any such action and the terms of Section 12.10.2(c) above shall apply.

12.11.3 **Settlement.** The Party controlling the defense of a Challenge pursuant to Sections 12.11.1 and 12.11.2 shall have the exclusive right to settle any such Challenge without the consent of the other Party, unless such settlement would have a material adverse impact on the other Party (in which case the consent of such other Party shall be required). For purposes of this Section 12.11.3, any settlement that would involve the waiver of rights (including the rights to receive payments), or limits the scope, validity or enforcement of any intellectual property rights or interest, of such other Party shall be deemed a material adverse impact and shall require the consent of such other Party, such consent not to be unreasonably withheld.

12.11.4 **Counterclaims.** Notwithstanding the foregoing in this Article 12, Section 12.12 shall govern the rights and obligations of the Parties with respect to a counterclaim brought in response to an action to abate an Infringement.

12.12 **Defense of Third Party Infringement Claims.** In the event that a claim is brought against either Party alleging the infringement, violation or misappropriation of any Third Party intellectual property right based on the Manufacture, use, sale or importation of a Therapeutic Product(s), the Parties shall promptly meet to discuss the defense of such claim, and the Parties shall, as appropriate, enter into a joint defense agreement with respect to the common interest privilege protecting communications regarding such claim in a form reasonably acceptable to the Parties.

12.13 **Common Interest Disclosures.** With regard to any information or opinions disclosed pursuant to this Agreement by one Party to each other regarding intellectual property or technology owned by Third Parties, the Parties agree that they have a common legal interest in determining whether, and to what extent, Third Party intellectual property rights may affect the conduct of the Initial Collaboration Research Program, Additional Collaboration Research Program, or Collaboration Programs, or Therapeutic Products, and have a further common legal interest in

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defending against any actual or prospective Third Party claims based on allegations of misuse or infringement of intellectual property rights relating to the conduct of the Initial Collaboration Research Program, Additional Collaboration Research Program, or Collaboration Programs or Therapeutic Products. Accordingly, the Parties agree that all such information and materials obtained by Poseida and Roche from each other will be used solely for purposes of the Parties' common legal interests with respect to the conduct of the Agreement. All information and materials will be treated as protected by the attorney-client privilege, the work product privilege, and any other privilege or immunity that may otherwise be applicable. By sharing any such information and materials, neither Party intends to waive or limit any privilege or immunity that may apply to the shared information and materials. Neither Party shall have the authority to waive any privilege or immunity on behalf of the other Party without such other Party's prior written consent, nor shall the waiver of privilege or immunity resulting from the conduct of one Party be deemed to apply against any other Party. Notwithstanding the foregoing, neither Party's attorney represents the other Party.

ARTICLE 13 **Representations, Warranties and Covenants**

13.1 **Mutual Representations, Warranties and Covenants.** Each Party represents, warrants and covenants (where expressly provided in 13.1.5 and 13.1.7) to the other Party that:

13.1.1 as of the Execution Date, it is validly organized under the laws of its jurisdiction of incorporation;

13.1.2 as of the Execution Date, except for HSR Filing, it has obtained all necessary consents, approvals and authorizations of all governmental authorities and other persons or entities required to be obtained by it in connection with its execution of this Agreement;

13.1.3 as of the Execution Date, the execution, delivery and performance of this Agreement have been duly authorized by all necessary corporate action on its part;

13.1.4 as of the Execution Date, it has the legal right and power to enter into this Agreement and to fully perform its obligations hereunder;

13.1.5 as of the Execution Date and from and after the Effective Date during the Term, it has followed and will follow reasonable commercial practices common in the industry designed to protect its proprietary and confidential information, including requiring its employees, consultants and agents to be bound in writing by obligations of confidentiality and non-disclosure, and requiring its employees, consultants and agents to assign to it any and all inventions and discoveries discovered or conceived by such employees, consultants or agents within the scope of and during their employment or in the course of providing services for such Party, and only disclosing proprietary and confidential information to Third Parties pursuant to written confidentiality and non-disclosure agreements;

13.1.6 as of the Execution Date, the performance of its obligations will not conflict with such Party's charter documents or any agreement, contract or other arrangement to which such Party is a party; and

13.1.7 from and after the Effective Date, neither Party nor any of its Affiliates will use in any capacity, in connection with the pre-clinical or clinical development activities to be performed under this Agreement, any individual or entity that has been debarred pursuant to Section 306 of the FFDCFA, or who is the subject of a conviction described in such section. Each Party agrees to inform the other Party in writing immediately if, to its actual knowledge, it or any individual or entity that is performing such activities by or on behalf of the informing Party hereunder is debarred or is the subject of a conviction described in Section 306, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the knowledge of the informing Party and its Affiliates, is threatened in writing, relating to the debarment or conviction of the informing Party or any individual or entity that is performing such activities by or on behalf of the informing Party hereunder.

13.2 **Poseida Additional Representations, Warranties and Covenants.** Poseida also represents, warrants and covenants (where expressly provided) to Roche that:

13.2.1 as of the Execution Date, it has the legal right and power to grant the licenses, rights, and interests granted to Roche hereunder;

13.2.2 it will not grant during the Term, any right, license or interest in or to the Poseida Background IP, Joint IP or Licensed Technologies, or any portion thereof, inconsistent with the rights, licenses, or interests granted to Roche herein in any material respect;

13.2.3 as of the Execution Date, it Controls sufficient right, title and interest in the Poseida Background IP existing as of the Execution Date, or otherwise has the rights therein sufficient to perform its obligations under this Agreement;

13.2.4 as of the Execution Date, except as set forth in Exhibit 13.2.4, the Poseida Background IP existing as of the such Execution Date is free and clear of all liens, claims, security interests, and other encumbrances of any kind (including any royalties, license fees or other amounts required to be paid to any Third Party) that would reasonably be expected to materially and adversely affect the licenses granted to Roche hereunder in material respects, except for fees payable pursuant to the Third Party In-License Agreements existing as of the Execution Date;

13.2.5 as of the Execution Date, Poseida has not entered into any agreements with any Third Party under which Know-How or Patent rights licensed to Roche hereunder are licensed (or an option to such license is granted) to Poseida except for (a) the Third Party In-License Agreement existing as of the Execution Date, and (b) agreements entered into with vendors and service providers in the ordinary course of business that may include license grants to Poseida;

13.2.6 as of the Execution Date, to the actual knowledge of Poseida, no activities of any Third Parties are infringing or misappropriating any Poseida Background IP or Licensed Technologies existing as of the Execution Date (including any pending patent applications and registrations therein as if such applications or registrations were to issue or become registered);

13.2.7 as of the Execution Date, Poseida has no actual knowledge of any threatened (in writing) or pending actions, lawsuits, claims or arbitration proceedings against Poseida that could reasonably be expected to materially and adversely affect the practice of the Know-How or Patent rights licensed to Roche hereunder existing as of the Execution Date or the conduct of the Tier 1

Development Plans, Tier 1 Process Development Plans, Initial Collaboration Research Plan, Additional Collaboration Research Plan, Collaboration Research Plans, Early Development Collaboration Plans or Study Plan, or the use of Poseida's Materials therein, in each case as contemplated by the Parties as of the Execution Date under this Agreement;

13.2.8 Poseida shall use Commercially Reasonable Efforts to maintain in effect all license agreements between Poseida and Third Parties that are in effect as of the Execution Date and material to the practice of the Poseida Background IP pursuant to the Tier 1 Development Plans, Tier 1 Process Development Plans, Initial Collaboration Research Plan, Collaboration Research Plans, Early Development Collaboration Plans, Study Plan or the licenses granted Roche hereunder, including the Third Party In-License Agreements existing as of the Execution Date, and shall not amend, waive or otherwise modify such agreements in a way that materially impairs Poseida's ability to perform its obligations hereunder or Roche's rights (including the scope of the intellectual property licensed to Roche) hereunder, without Roche's prior written consent, not to be unreasonably withheld or delayed;

13.2.9 Poseida will not knowingly incorporate in any Therapeutic Product or the Manufacturing Process of any Therapeutic Product, any intellectual property or confidential information of a Third Party that is not Controlled by Poseida or Roche, unless specifically discussed and approved in writing by Roche in advance;

13.2.10 Poseida has obtained (or will timely obtain) all informed consents, permissions and approvals that are necessary for Poseida to conduct the activities under the Tier 1 Development Plans, Tier 1 Process Development Plans, Initial Collaboration Research Plan, Additional Collaboration Research Plan, Collaboration Research Plans and Early Development Collaboration Plans and provide the data (including all clinical trial data), provided (for the avoidance of doubt) that any such transferred data that relates to patients or other clinical trial participants shall be in de-identified form in accordance with Section 10.9 of this Agreement to Roche and permit Roche to use such data for all purposes contemplated herein, including to research, develop and commercialize Therapeutic Products; and

13.2.11 Poseida covenants that it shall not amend a [\[***\] in a way that would materially adversely affect the rights granted by Poseida to Roche under this Agreement.](#)

13.3 **Roche Additional Representations and Warranties.** Roche also represents, warrants and covenants (where expressly provided) to Poseida that:

13.3.1 as of the Execution Date, Roche has the legal right and power to grant the licenses, rights, and interests granted to Poseida hereunder; and

13.3.2 as of the Execution Date, Roche has no actual knowledge of any threatened or pending actions, lawsuits, claims or arbitration proceedings that could reasonably adversely affect the use of Materials provided by Roche in the Tier 1 Development Plans, Tier 1 Process Development Plans, Initial Collaboration Research Plan, or Study Plan, as contemplated under this Agreement, prior to Program Transition; provided, however, that nothing in this Section 13.3.2

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shall be interpreted as requiring Roche to have undertaken any inquiries or to have obtained any freedom to operate opinion.

13.4 **Effective Date.** During the period from the Execution Date until the Effective Date, Poseida shall promptly inform Roche in writing if and when Poseida or any of its Affiliates becomes aware that any of the representations and warranties made by Poseida pursuant to Section 13.1 or 13.2 as of the Execution Date are no longer true and correct in any material respects if made on and as of the date of such notice.

13.5 **Disclaimers.** EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL REPRESENTATIONS OR WARRANTIES OF ANY KIND WITH RESPECT TO THE SUBJECT MATTER OF THIS AGREEMENT, EITHER EXPRESS OR IMPLIED, INCLUDING ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE; AND MATERIALS PROVIDED UNDER SECTIONS 3.5.1, 5.3 AND 5.4.2 ARE PROVIDED “AS IS”.

ARTICLE 14 Indemnification

14.1 **Indemnification by Poseida.** Subject to Section 14.3, Poseida shall indemnify, defend and hold each of Roche, its Affiliates and their respective directors, officers, and employees, and the successors and assigns of any of the foregoing (“**Roche Indemnitees**”), harmless from and against any and all liabilities, damages, settlements, penalties, fines, costs or expenses (including, without limitation, reasonable attorneys’ fees and other expenses of litigation) (collectively, “**Loss**” or “**Losses**”) as a result of any Third Party claims, suits, actions, demands or judgments (“**Third Party Claims**”) arising out of [***].

14.2 **Indemnification by Roche.** Subject to Section 14.3, Roche shall indemnify, defend and hold each of Poseida, its Affiliates and their respective directors, officers, and employees, and the successors and assigns of any of the foregoing (“**Poseida Indemnitees**”), harmless from and against any and all Losses as a result of any Third Party Claims arising out of [***]

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[***].

14.3 **Procedure.** If a Party intends to claim indemnification under this Agreement (the “**Indemnitee**”), it shall promptly notify the other Party (the “**Indemnitor**”) in writing of such alleged Loss. The failure to deliver written notice to the Indemnitor within a reasonable time after the commencement of any such action, to the extent prejudicial to its ability to defend such action, shall relieve the Indemnitor of any obligation to the Indemnitee under this Section 14.3 with regard to such action, but the omission to deliver notice to the Indemnitor shall not otherwise relieve the Indemnitor of any liability that it may have to any Indemnitee otherwise under this Article 14. Only Roche and Poseida may claim indemnity under this Agreement (on its own behalf or on behalf of its Indemnitees), and other Indemnitees may not directly claim indemnity hereunder. The Indemnitor shall have the right to control the defense thereof with counsel of its choice and reasonably acceptable to Indemnitee. Any Indemnitee shall have the right to retain its own counsel at its own expense for any reason, provided, however, that if the Indemnitee shall have reasonably concluded, based upon reasonable advice from outside legal counsel, that there is a conflict of interest between the Indemnitor and the Indemnitee in the defense of such action, the Indemnitor shall pay the reasonable fees and expenses of one law firm selected by Indemnitee and reasonably acceptable to Indemnitor to serve as counsel for the Indemnitee as part of Losses. The Indemnitee, its employees and agents, shall reasonably cooperate with the Indemnitor and its legal representatives in the investigation of any Third Party Claims covered by this Agreement. The obligations of this Article 14 shall not apply to amounts paid in settlement of any claim, demand, action or other proceeding if such settlement is effected without the consent of the Indemnitor, which consent shall not be unreasonably withheld, conditioned, or delayed. The Indemnitor shall not, without the written consent of the Indemnitee, effect any settlement of any Third Party Claims, unless such settlement is solely for monetary damages and includes an unconditional release of the Indemnitee from all liability on claims that are the subject matter of such proceeding.

14.4 **Insurance.** Each Party shall maintain insurance coverage as set forth in this Section 14.4 at its own cost; provided, however, Roche has the right, in its sole discretion, to self-insure, in part or in whole, for any such coverage.

14.4.1 **Commercial General Liability.** During the Term and for [***] thereafter, each Party shall maintain commercial general liability insurance (a) combined single limit for bodily injury and property damage liability, in the minimum amount per occurrence of [***] per occurrence and [***] in the aggregate, (b) workers’ compensation insurance, according to applicable laws and (c) employers’ liability insurance, in the minimum amount of [***], all commencing as of the Effective Date.

14.4.2 **Product/Clinical Trial Liability.** Commencing not later than [***] prior to the first use in humans of the first Therapeutic Product, each Party, its Affiliates or Sublicensees (as applicable) shall have and maintain such type and amounts of products/clinical trial liability insurance covering its development, Manufacture, use, and sale of Therapeutic Products as is normal and customary in the industry generally for parties similarly situated, but, in any event, with a minimum combined single limit per occurrence for products/clinical trials liability as

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follows a minimum limit of [***] for any period during which such Party, its Affiliates or Sublicensees is conducting a clinical trial(s) with any Therapeutic Product(s) or is commercializing any Therapeutic Product(s).

14.4.3 **Insurance Coverage.** The insurance policies set forth in Sections 14.4.1 and 14.4.2 for such coverage shall be an occurrence form, but if only a claims made form is available to a Party, such Party shall maintain such coverage for at least [***] after the later of (a) termination or expiration of this Agreement or (b) such Party has no further obligations under this Agreement. Insurance coverage shall be maintained with an insurance company or companies having an A.M. Best's rating (or its equivalent) of A-VII or better. On written request, Poseida shall provide to Roche certificates of insurance evidencing the insurance coverage required under this Section 14.4. Poseida shall provide to Roche at least [***] notice of any cancellation, nonrenewal or material adverse change in any of the required insurance coverages. The limits of a Party's insurance or self-insurance coverage shall not limit the Party's liability, including under the indemnification provisions of this Agreement.

14.5 **Limitation of Damages.** IN NO EVENT SHALL EITHER PARTY OR ITS AFFILIATES BE LIABLE TO THE OTHER PARTY FOR SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL, EXEMPLARY OR PUNITIVE DAMAGES OR LOST PROFITS OR BUSINESS INTERRUPTION ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES, WHETHER BASED ON CONTRACT, TORT OR ANY OTHER LEGAL THEORY, EXCEPT IN RESPECT OF (A) THE INDEMNIFICATION OBLIGATION OF SUCH PARTY IN RESPECT OF THIRD PARTY CLAIMS UNDER THE PROVISIONS OF THIS ARTICLE 14, OR (B) DAMAGES AVAILABLE FOR BREACH OF ARTICLE 10.

ARTICLE 15

Term; Termination

15.1 **HSR and Other Government Filings.** If Roche determines that an HSR Filing is necessary before the Effective Date of this Agreement or the effective dates of the exclusive licenses contemplated in Section 6.2.1 or 6.3.1(b), each Party shall, within ten (10) Business Days of the Execution Date (or such later time as may be agreed to in writing by the Parties), file with the US Federal Trade Commission ("FTC") and the Antitrust Division of the US Department of Justice ("DOJ"), any HSR Filing required of it under the HSR Act. The Parties shall seek early termination of the waiting period under the HSR Act (if available) unless otherwise agreed by the Parties in writing. Each Party will use [***] to do so, or cause to be done, all things necessary or advisable to, as promptly as practicable, take all actions necessary to make the filings required of such Party or its Affiliates under the HSR Act and obtain the requisite compliance of such Party with the HSR Act. The Parties shall use [***] to (w) cooperate with one another in the preparation of any such HSR Filing; (x) timely keep the other reasonably informed of any material communication received by such Party from, or given by such Party to, the DOJ or FTC regarding any of the transactions contemplated by this Agreement, and promptly furnish the other with copies of all such written communications; (y) permit the other to review in advance any written communication to be given by it to the DOJ or FTC and, to the extent permitted by the DOJ or FTC, give the other the opportunity to attend and participate in any in-person, video, or telephonic meetings and conferences; and (z) cooperate in the filing of any memoranda, white

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papers, submissions, or other written communications defending the transactions contemplated herein or responding to reasonable requests by the DOJ or FTC, permitting the other Party to review in advance and considering in good faith the other Party's reasonable comments. Materials provided pursuant to this Section 15.1 may be restricted to outside counsel and redacted to remove references to privileged information or as necessary to comply with contractual arrangements. Roche shall be responsible for the filing fees, and each Party shall be responsible for the costs and expenses of its own legal and other advice in preparing and conducting the HSR Filing, including responding to the relevant governmental authorities. Neither Party shall commit to or agree with the DOJ or FTC to stay, toll or extend any applicable waiting period or pull and refile under the HSR Act, without the prior written consent of the other Party. If the Parties make an HSR Filing under this Agreement, then the Agreement shall terminate: (A) at the election of either Party, immediately upon written notice to the other Party, if the FTC or the DOJ seeks a preliminary injunction under the applicable antitrust laws against the Parties to enjoin the transactions contemplated by this Agreement; or (B) at the election of either Party, immediately upon written notice to the other Party, in the event that the expiration or termination of (i) all applicable waiting periods and requests for information (and any extensions thereof) under the HSR Act and (ii) any agreements with the FTC or DOJ not to consummate the transactions contemplated by this Agreement, do not occur on or prior to [***] after the effective date of the HSR Filing. In the event of such termination, this Agreement shall be of no further force and effect; provided, however, Article 10, Article 11, Article 14, Article 16 and Sections 17.1, 17.2, 17.4, 17.5 and 17.7-17.14 (inclusive) shall survive with respect any rights that accrued to the benefit of a Party prior to such termination.

15.2 **Term.** The term of this Agreement (the “**Term**”) shall commence on the Effective Date and, unless earlier terminated as provided in this Article 15, shall continue in full force and effect, on a country-by-country, Therapeutic Product-by-Therapeutic Product or Licensed Product-by- Licensed Product basis until there is no remaining royalty payment or other payment obligation in such country with respect to such Therapeutic Product or Licensed Product under Article 8, at which time this Agreement shall expire with respect to such Therapeutic Product or Licensed Product in such country. Unless earlier terminated in this Article 15, the Term shall expire on the date this Agreement has expired in its entirety with respect to all Therapeutic Products and all Licensed Products in all countries worldwide.

15.3 **Termination by Either Party for Uncured Material Breach.**

15.3.1 **Termination by Either Party.** Either Party may terminate this Agreement in its entirety, or with respect to a particular Therapeutic Program or Licensed Product, by written notice to the other Party for any material breach of this Agreement by the other Party if, in the case of remediable breach, such material breach is not cured within ninety (90) days after the breaching Party receives written notice of such material breach from the non-breaching Party; provided, that if such material breach is not capable of being cured within such 90-day period, the cure period shall be extended for such amount of time that the Parties may agree in writing is reasonably necessary to cure such material breach, so long as (a) the breaching Party is making diligent efforts to do so, (b) the Parties agree on an extension within such 90-day period, and (c) such extension is no more than additional ninety (90) days. Notwithstanding anything to the contrary herein, if the allegedly breaching Party in good faith either disputes (i) whether a breach is material or has occurred or (ii) the alleged failure to cure such material breach, and provides written notice of that

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Dispute to the other Party within the cure period, then the matter will be addressed under the dispute resolution provisions in Article 16, and the Party alleging material breach may not so terminate this Agreement (in whole or in part) until it has been determined under Article 16 that the allegedly materially breaching Party is in material breach of this Agreement, and such breaching Party further fails to cure such breach within ninety (90) days after the conclusion of such dispute resolution procedure. For the avoidance of doubt, where the uncured material breach is related solely to a particular Therapeutic Program, any termination hereunder shall be limited to terminating the Agreement solely with respect to that Therapeutic Program and not to the Agreement in its entirety. Likewise, for the avoidance of doubt, where the uncured material breach is related solely to a particular Licensed Product, any termination hereunder shall be limited to terminating the Agreement solely with respect to that Licensed Product and not to the Agreement in its entirety.

15.3.2 **Termination by Roche Relating to Therapeutic Program.** In the event that Poseida's uncured wilful material breach (which, if disputed, is submitted to and finally adjudicated as such pursuant to Section 15.3.1 and Article 16) with respect to a Therapeutic Program occurs prior to commencement of Program Transition for such program, and Roche has the right to terminate this Agreement with respect to such Therapeutic Program pursuant to Section 15.3.1, then in lieu of terminating the Agreement with respect to such Therapeutic Program in accordance with Section 15.3.1, Roche may, upon written notice to Poseida, instead terminate Poseida's further work on such Therapeutic Program and trigger Program Transition and Technology Transfer for such Therapeutic Program, in which case Poseida will promptly complete such Program Transition and Technology Transfer with respect to such Therapeutic Program [***]

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15.4 **Termination by Either Party for Insolvency or Bankruptcy.** Either Party may terminate this Agreement effective on written notice to the other Party upon the liquidation, dissolution, winding-up, (income statement) insolvency, bankruptcy, or filing of any petition therefor, appointment of a receiver, custodian or trustee, or any other similar proceeding, by or of the other Party where such petition, appointment or similar proceeding is not dismissed or vacated within ninety (90) days. All rights and licenses granted pursuant to this Agreement are, for purposes of Section 365(n) of Title 11 of the United States Code or any foreign equivalents thereof (as used in this Section 15.4, “**Title 11**”), licenses of rights to “intellectual property” as defined in Title 11. Each Party in its capacity as a licensor hereunder agrees that, in the event of the commencement of bankruptcy proceedings by or against it under Title 11, (a) the other Party, in its capacity as a licensee of rights under this Agreement, shall retain and may fully exercise all of such licensed rights under this Agreement (including as provided in this Section 15.4) and all of its rights and elections under Title 11 and (b) the other Party shall be entitled to a complete duplicate of all embodiments of such intellectual property, and such embodiments, if not already in its possession, shall be promptly delivered to the other Party (i) upon any such commencement of a bankruptcy proceeding, unless the bankrupt Party elects to continue to perform all of its obligations under this Agreement, or (ii) if not delivered under (i), immediately upon the rejection of this Agreement by or on behalf of the bankrupt Party.

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15.5 **Elective Termination by Roche; Discontinuation, Cessation.** Roche shall also have the right to terminate this Agreement with respect to a particular Therapeutic Program, the R&D License or the Commercial License, or to terminate further work of the Parties under the Initial Collaboration Research Program or the Additional Collaboration Research Program (if applicable), in each case in its sole discretion, at any time by providing written notice to Poseida; such termination to be effective [***] after such notice. Notwithstanding the foregoing, Roche shall have the right to terminate this Agreement in its entirety, in its sole discretion, at any time by providing written notice to Poseida; such termination to be effective [***] after such notice.

If, after a Program Transition of the applicable Therapeutic Program, (a) Roche has made a formal determination by senior executives with management responsibility for the applicable Therapeutic Program to discontinue further research, development, Manufacturing, and commercialization of all Therapeutic Programs Directed To [***] or (b) Roche discontinued all research, development, Manufacturing and commercialization activities for all Therapeutic Programs Directed To [***] then Roche shall promptly notify Poseida and, upon such notice, Roche shall be deemed to have terminated this Agreement under this Section 15.5 with respect to such Therapeutic Program.

15.6 **Termination by Poseida for Patent Challenge.** Except to the extent the following is unenforceable under the laws of a particular jurisdiction, Poseida may terminate this Agreement with respect to any Patent [***] or, with respect to any Patent [***], is licensed by Poseida to Roche under this Agreement, upon written notice to Roche if Roche or its Affiliates or Sublicensees, individually or in association with any other person or entity, commences a legal action anywhere in the world challenging the validity or enforceability of such Patent; provided that, [***].

15.7 **Effects of Termination.**

15.7.1 **Accrued Rights and Obligations.** Expiration or termination of this Agreement for any reason shall not release either Party from any liability which, as of the effective date of such expiration or termination, had already accrued to the other Party or which is attributable to a period prior to such termination, nor preclude either Party from pursuing any rights and remedies it may

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have hereunder or at law or in equity which accrued or are based upon any event occurring prior to the effective date of such expiration or termination.

15.7.2 **Termination of Licenses; [***].** Upon any termination of this Agreement, whether in its entirety or with respect to a particular Therapeutic Program, Licensed Product or license under Section 6.6.1(a), 6.6.2(b), or 6.6.4(b), subject to Sections 8.8.5, (a) all licenses set forth in this Agreement shall terminate, in their entirety or with respect to such Therapeutic Program, Licensed Product or license under Section 6.6.1(a), 6.6.2(b), or 6.6.4(b), as applicable, as of the effective date of such termination, and [***].

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- 15.7.3 [***]
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[***] = **Certain Confidential Information Omitted**

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[***] = Certain Confidential Information Omitted

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15.7.4 **Inventory at Termination.** Upon termination of this Agreement in whole, as to a Therapeutic Program after Marketing Authorization is obtained for one or more Therapeutic Products in the relevant Therapeutic Program(s) or as to Licensed Technologies after Marketing Authorization is obtained for one or more Licensed Products, Roche and its Affiliates and Sublicensees shall have the right to continue to Manufacture and commercialize any such affected Therapeutic Product(s) or Licensed Products for any existing patients who, as of the effective date of termination, has commenced the process, or is scheduled to commence the process, to receive treatment with such Therapeutic Product(s) or Licensed Product(s), for a period of no more than [***] after the effective date of termination (the “**Sell-Off Period**”). Such continued sale of such Therapeutic Product(s) or Licensed Product(s) shall be subject to the applicable royalty payments due under this Agreement, and any other applicable provisions of this Agreement, and Poseida covenants not to sue Roche or its Affiliates or Sublicensees for infringement or misappropriation of any of the Patents or Know-How that were licensed by Poseida to Roche immediately prior to such termination solely during the Sell-Off Period for all existing patients treatment and solely with respect to such activities conducted by Roche or its Affiliates or Sublicensees pursuant to this Section 15.7.3.

15.7.5 **Continuation of Sublicenses.** In the event of a termination of this Agreement by Poseida, any existing, permitted sublicense granted by Roche under this Agreement shall continue in full force and effect, provided that, if the applicable termination was pursuant to Section 15.3 or 15.6, the permitted Sublicensee did not cause the uncured material breach or patent challenge that gave rise to such termination and, in any event, agrees to be bound by all the terms and conditions of this Agreement that are applicable to such permitted Sublicensee including rendering directly to Poseida all payments and other obligations due to Poseida related to such sublicense (including all milestone payments and royalty payments); provided further that Poseida is not obligated to assume any obligations under such sublicense that are greater than the obligations contained within this Agreement.

15.7.6 **Termination Prior to Program Transition.** Unless otherwise requested in writing by Roche, promptly following its receipt or delivery (as applicable) of a notice of termination of this Agreement (in its entirety or with respect to a Therapeutic Program) prior to

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Program Transition of the Therapeutic Program(s) that the subject of such termination, Poseida shall promptly wind down any and all activities conducted by or on behalf of Poseida with respect to such Therapeutic Program(s) that use or incorporate Roche Background IP or Roche's Confidential Information.

15.7.7 **Survival.** In addition to any provisions specified in this Agreement as surviving under the applicable circumstances, the following Articles and Sections shall survive any termination or expiration of this Agreement (for the applicable period if so specified therein): Article 1, Article 9 Article 10, Article 13, Article 14, Article 17 and Sections 3.8, 6.4, 6.5, 6.6.3, 6.12, 12.9, 8.2.1 (only with respect to maintaining records and related audit rights), 8.4.3 (only with respect to maintaining records and related audit rights), 12.2, 12.3, 12.4.2(a) (only with respect to Joint Patents), 12.4.2(b) (only with respect to Joint Patents), 12.4.2(c) (only with respect to Joint Patents), 15.7.3 (and 16.4, 16.6, as applicable), 15.7.5 and 15.7.7.

ARTICLE 16

Dispute Resolution

16.1 **Disputes.** Poseida and Roche recognize that a dispute, controversy or claim of any nature whatsoever arising out of or relating to this Agreement, or the formation, applicability, breach, termination, validity or enforceability thereof (each, a "**Dispute**"), may from time to time arise. Unless otherwise specifically recited in this Agreement, including Article 2, such Disputes between Poseida and Roche will be resolved in accordance with this Article 16. A Dispute shall first be referred to the Alliance Managers for both Parties for attempted resolution. If the Alliance Managers are unable to resolve the Dispute within [***] (or such later time as agreed to by the Parties) following the date of such referral (as evidenced in a writing identifying the subject matter of the Dispute and referencing this Section 16.1), either Poseida or Roche shall have the right, by written notice to the other, to have such Dispute referred to a Vice President of Roche and the Chief Executive Officer of Poseida (or their designees who have been duly authorized to resolve such Dispute) for attempted resolution through good faith discussions. In the event the designated officers, or their respective designees, are not able to resolve such Dispute within [***] of such other Party's receipt of such written notice, either Party shall have the right to initiate the dispute resolution procedures set forth in Section 16.2.

16.2 Arbitration.

16.2.1 **Rules.** Except as otherwise expressly provided in this Agreement (including under Sections 16.3 and 16.4), the Parties agree that any Dispute not resolved internally by the Parties pursuant to Section 16.1 shall be resolved through binding arbitration conducted by JAMS in accordance with the Comprehensive Arbitration Rules and Procedures of JAMS as in effect at the time of the arbitration, (for purposes of this Article 16, the "**Rules**"), except as modified in this Agreement, applying the substantive law specified in Section 17.1. Any Dispute concerning the propriety of the commencement of the arbitration shall be finally settled by the arbitrators.

16.2.2 **Arbitrators; Seat.** Within [***] after the commencement of the arbitration, Poseida and Roche shall each select one (1) arbitrator, and the two (2) arbitrators so selected shall choose a third arbitrator within [***] of the second arbitrator's appointment. All three (3) arbitrators shall serve as neutrals, be impartial and independent and

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have at least [***] of (a) dispute resolution experience (including judicial experience) or (b) legal or business experience in the biotech or pharmaceutical industry. In any event, at least [***] shall satisfy the foregoing experience requirement under clause (b). An arbitrator shall be deemed to meet these qualifications unless a Party objects in good faith within [***] after an arbitrator is selected. If a Party fails to timely select its arbitrator, or if the Parties' arbitrators cannot timely agree on the third, the necessary appointments shall be made by JAMS in accordance with the Rules. Once appointed by a Party, such Party shall have no ex parte communication with its appointed arbitrator. The seat, or legal place of arbitration, shall be [***]. The arbitration proceedings and all pleadings and written evidence shall be in the English language. Any written evidence originally in another language shall be submitted in English translation accompanied by the original or a true copy thereof.

16.2.3 **Procedures; Awards.** Unless agreed otherwise by the Parties, the Parties shall have [***] from the appointment of the last to be appointed of the three (3) arbitrators to submit their positions to the arbitrators, and the Parties shall have a hearing before the arbitrators within [***] of such submission. The arbitrators shall be instructed and required to render a written, binding, non-appealable resolution and award on each issue that clearly states the basis upon which such resolution and award is made. The written resolution and award shall be delivered to the Parties as expeditiously as possible, but in no event more than [***] after the later of the conclusion of the last hearing or the final written submissions, unless otherwise agreed by the Parties or extended by the arbitrators for good cause. The award shall be final and binding and the Parties agree to carry out any award without delay. Judgment upon such award may be entered in any court of competent jurisdiction. Each Party agrees that, notwithstanding any provision of applicable law or of this Agreement, it will not request, and the arbitrators shall have no authority to award, damages against any Party that are prohibited under Section 14.5. The Parties acknowledge that this Agreement evidences a transaction involving interstate commerce. Notwithstanding Section 17.1, with respect to the applicable substantive law, any arbitration conducted pursuant to the terms of this Agreement shall be governed by the Federal Arbitration Act (9 U.S.C. §§ 1 *et. seq.*).

16.2.4 **Costs.** The prevailing Party, as determined by the arbitrators, shall be entitled to (a) its share of fees and expenses of the arbitrators and JAMS and (b) its attorneys' fees and associated costs and expenses. In determining which Party "prevailed," the arbitrators shall consider (i) the significance, including the financial impact, of the claims prevailed upon and (ii) the scope of claims prevailed upon, in comparison to the total scope of the claims at issue. If the arbitrators determine that, given the scope of the arbitration, neither Party "prevailed," the arbitrators shall order that the Parties (A) share equally the fees and expenses of the arbitrators and JAMS and (B) bear their own attorneys' fees and associated costs and expenses.

16.2.5 **Interim Equitable Relief.** Notwithstanding anything to the contrary in this Section 16.2, in the event that a Party reasonably requires relief on a more expedited basis than would be possible pursuant to the procedure set forth in this Article 16, such Party may seek a temporary injunction or other interim equitable relief in a court of competent jurisdiction pending the ability of the arbitrators to review the decision under this Section 16.2. Such court shall have no jurisdiction or ability to resolve Disputes beyond the specific issue of temporary injunction or other interim equitable relief.

[***] = Certain Confidential Information Omitted

16.2.6 **Protective Orders; Arbitrability.** At the request of either Party, the arbitrators shall enter an appropriate protective order to maintain the confidentiality of information produced or exchanged in the course of the arbitration proceedings. The arbitrators shall have the power to decide all questions of arbitrability, including the scope and applicability of this Agreement to arbitrate.

16.3 **Subject Matter Exclusions.** Notwithstanding the provisions of Section 16.2, any Dispute not resolved internally by the Parties pursuant to Section 16.1 that involves the scope, validity or infringement of a Patent (a) that is issued or filed in the United States shall be subject to actions before the United States Patent and Trademark Office or submitted exclusively to the federal court located in the jurisdiction of the district where any of the defendants resides; and (b) that is issued or filed in any other country shall be brought before an appropriate regulatory or administrative body or court in that country, and the Parties hereby consent to the jurisdiction and venue of such courts and bodies.

16.4 **Baseball-Style Arbitration.** Notwithstanding anything to the contrary in this Article 16, upon a failure of the Parties to agree as set forth in Section 15.7.3(b) within the relevant time period specified therein, in the event Poseida elects to resolve the issue through baseball-style arbitration, Poseida shall notify Roche of its decision to initiate the arbitration proceeding pursuant to this Section 16.4 through written notice to Roche within [\[***\] of the end of such period.](#)

16.4.1 Within [***] following the Roche's receipt of such notice, the Parties shall use commercially reasonable efforts to agree on an independent (e.g., having no prior relationship with either Party or its Affiliates, and not having been engaged by either Party or its Affiliates previously for arbitration) and impartial baseball arbitrator with at least [***] of experience in the licensing of pharmaceutical (or biopharmaceutical) compounds or products. If the Parties cannot agree on such arbitrator within such time period, each Party shall nominate one arbitrator within such [***] period, and the two arbitrators so selected shall nominate the final arbitrator within [***] of their nomination. If the two arbitrators so selected cannot agree on the final arbitrator, the third party arbitrator shall be appointed by the Senior Vice President of JAMS, US West Region or another mutually agreed arbitral body or otherwise by mutual agreement of the senior executives of the Parties. For the avoidance of doubt, it is understood and agreed that such final arbitrator should have at least [***] of experience in the licensing of pharmaceutical (or biopharmaceutical) compounds or products.

16.4.2 Within [***] after the later of the appointment of the agreed arbitrator or the appointment of the final arbitrator, the arbitrator(s) shall set a date for the merits hearing, which date shall be no more than [***] days after the last appointment of the arbitrator under Section 16.4 above.

16.4.3 The arbitration shall be "baseball-style" arbitration; accordingly, at least [***] prior to the merits hearing, each Party shall provide the arbitrator(s) and the other Party with a form of the [***], in each case consistent with Section 15.7.3(b), and argument in support thereof. Such proposal and supporting argument may be no more than one hundred (100) pages, and must clearly provide and identify the Party's position with respect to the disputed matter(s).

[***] = Certain Confidential Information Omitted

16.4.4 [***] in advance of the merits hearing (described in Section 16.4.5 below), the Parties shall submit to the arbitrator(s) and exchange response briefs of no more than fifteen (15) pages, provided that the page limit may be enlarged upon application to the arbitrator(s) for good cause. In addition, at least [***] in advance of the merits hearing (described in Section 16.4.5 below), each Party may submit to the arbitrator(s) and the other Party a revised version of its proposed Transfer Agreement, including the Reversion License, in each case consistent with Section 15.7.3(b), (together with a redline showing the changes from its prior submitted draft proposal). The Parties' briefs may include or attach relevant exhibits in the form of documentary evidence, any other material voluntarily disclosed to the submitting Party in advance, or publicly available information. The Parties' briefs may also include or attach demonstratives and/or expert opinion based on the permitted documentary evidence. Neither Party may have any other communications (either written or oral) with the arbitrator(s) other than for the sole purpose of engaging the arbitrator(s) or as expressly permitted in this Section 16.4, except as requested by the arbitrator(s).

16.4.5 The merits hearing shall consist of a one (1) day hearing of no longer than eight (8) hours, such time to be split equally between the Parties, in the form of presentations by counsel and/or employees and officers of the Parties. No live witnesses shall be permitted except expert witnesses whose opinions were provided with the Parties' briefs.

16.4.6 No later than [***] following the merits hearing, the arbitrator(s) shall issue a written decision. The arbitrator(s) shall select one Party's proposed [***] as their decision, and shall not have the authority to render any substantive decision other than to select the proposed [***] submitted by either Roche or Poseida. The arbitrator(s) shall have no discretion or authority with respect to modifying the positions of the Parties. The arbitrator(s)'s decision shall be final and binding on the Parties and the written [***] selected by the arbitrator(s) shall constitute a binding agreement between the Parties that may be enforced in accordance with its terms. [***].

16.4.7 The violation of one of the time limits prescribed in this Section 16.4 by the arbitrator(s) shall not affect the arbitrator(s)'s competence to decide on the subject matter, and shall not affect the final and binding decision rendered by the arbitrator(s).

16.5 **Continued Performance.** Provided that this Agreement has not terminated or expired, the Parties agree to continue performing under this Agreement in accordance with its provisions, pending the final resolution of any Dispute.

16.6 **Confidentiality.** Except for purposes of confirming or challenging an award, or court proceedings to obtain interim relief, any and all activities conducted under this Article 16, including any proceedings and decisions hereunder, will be deemed Confidential Information of each of the Parties, and will be subject to Article 10, to the extent applicable in accordance with applicable law.

[***] = Certain Confidential Information Omitted

ARTICLE 17
Miscellaneous

17.1 **Choice of Law.** This Agreement shall be governed by and interpreted in accordance with the laws of [***], without reference to the principles of conflicts of laws. The United Nations Convention on Contracts for the International Sale of Goods shall not apply to the transactions contemplated by this Agreement.

17.2 **Notices.** Except as otherwise expressly provided in the Agreement, any notice required under this Agreement shall be in writing and shall specifically refer to this Agreement. Notices shall be sent via one of the following means and shall be effective (a) on the date of delivery, if delivered in person; (b) two (2) days after the date mailed if mailed by first class certified mail return receipt requested, postage prepaid to a destination within the same jurisdiction; (c) seven (7) days after the date mailed if mailed by registered or certified mail return receipt requested, postage prepaid to a destination outside the jurisdiction of the Party sending the notice; or (d) on the date of receipt, if sent by private express courier. Notices shall be sent to the other Party at the addresses set forth below. Either Party may change its addresses for purposes of this Section 17.2 by sending written notice to the other Party.

If to Roche:

F. Hoffmann-La Roche Ltd
Grenzacherstrasse 124
4070 Basel Switzerland
Attn: Legal Department
Email: To be provided by Alliance Manager

with required copies (which shall not constitute notice) to:

F. Hoffmann-La Roche Ltd
Attn: Alliance Manager, Pharma Partnering Grenzacherstrasse 124
4070 Basel Switzerland

If to Poseida:

Poseida Therapeutics, Inc. 9390 Towne Center Drive
San Diego, CA 92121
Attention: CEO & General Counsel Email: [***]

[***] = Certain Confidential Information Omitted

with required copies (which shall not constitute notice) to:

Cooley LLP
Reston Town Center 11951
Freedom Drive 14th Floor
Reston, VA 20190-5640
Attention: Kenneth Krisko Email: [***]

17.3 **Assignment.** Neither Party may assign or otherwise transfer, in whole or in part, this Agreement, without the prior written consent of the non-assigning Party, such approval not to be unreasonably withheld or delayed. Notwithstanding the foregoing, either Party may assign or transfer this Agreement without the consent of the other Party to (a) an Affiliate or (b) any purchaser of all or substantially all of the assets of such Party, or of all of its capital stock, or to any successor corporation or entity resulting from any merger or consolidation of such Party with or into such corporation or entity, provided that the party to which this Agreement is assigned or transferred expressly agrees in writing to assume and be bound by all obligations of the assigning Party under this Agreement and, without limitation, in connection with a Change in Control of Poseida. A copy of such written agreement by such assignee shall be provided to the non-assigning Party within [***] of execution of such assignment. The terms and conditions of this Agreement shall be binding upon, and shall inure to the benefit of, the Parties and their respective successors and permitted assigns. Any attempted assignment not in accordance with this Section 17.3 shall be null and void.

17.4 **Independent Contractors.** The Parties are independent contractors and nothing contained in this Agreement shall be deemed or construed to create a partnership, joint venture, employment, franchise, agency or fiduciary relationship between the Parties. Neither Roche nor Poseida has the authority to make any statements, representations or commitments of any kind, or to take any action, which will be binding on the other Party, without the prior written consent of the other Party.

17.5 **Actions of Affiliates.** Either Party may exercise its rights or perform its obligations under this Agreement personally or through one or more Affiliates, provided that such Party shall nonetheless be primarily liable for the performance of its Affiliates and for any failure by its Affiliates to comply with the restrictions, limitations and obligations set forth in this Agreement.

17.6 **Force Majeure.** Neither Party shall be deemed to have breached this Agreement for failure to perform its obligations under this Agreement, to the extent such failure results from causes beyond the reasonable control of the affected Party, such causes including acts of God, earthquakes, fires, floods, embargoes, wars, acts of terrorism, insurrections, riots, civil commotions, epidemics, pandemics, omissions or delays in action by any governmental authority, acts of a government or agency thereof and judicial orders or decrees, and any deadline or time period affected by such a force majeure event or a Party's failure to perform resulting therefrom shall be extended automatically by the number of days equal to the number of days that such force majeure or failure persisted. If such a force majeure event occurs, the Party unable to perform shall promptly notify the other Party of the occurrence of such event, and the Parties shall meet (in

[***] = Certain Confidential Information Omitted

person or telephonically) promptly thereafter to discuss the circumstances relating thereto. The Party unable to perform shall (a) provide reasonable status updates to the other Party from time to time; (b) use Commercially Reasonable Efforts to mitigate any adverse consequences arising out of its failure to perform; and (c) resume performance as promptly as possible. Further, in the event the end of any time period set forth herein falls (or any deadline herein otherwise expires) during the period beginning on December 25 of any Calendar Year in the Term and ending on January 1 of the following year, such time period (or deadline) shall be extended by [***], unless otherwise agreed in writing by the Parties.

17.7 **Integration.** Except to the extent expressly provided herein, this Agreement, including the Exhibits hereto, constitutes the entire agreement between the Parties relating to the subject matter of this Agreement and supersedes all previous oral and written communications between the Parties with respect to the subject matter of this Agreement, including the Prior NDA. In the event of any conflict or inconsistency between the body of this Agreement and an Exhibit, the terms and conditions of the body of this Agreement shall prevail.

17.8 **Amendment; Waiver.** Except as otherwise expressly provided herein, no alteration of or modification to this Agreement shall be effective unless made in writing and executed by an authorized representative of each Party. No course of dealing or failing of either Party to strictly enforce any term, right or condition of this Agreement in any instance shall be construed as a general waiver or relinquishment of such term, right or condition. The observance of any provision of this Agreement may be waived (either generally or any given instance and either retroactively or prospectively) only with the written consent of the Party granting such waiver.

17.9 **Severability.** The Parties do not intend to violate any public policy or statutory or common law. However, if any sentence, paragraph, clause or combination or part thereof of this Agreement is in violation of any law or is found to be otherwise unenforceable or invalid in any respect in any jurisdiction, the Parties shall substitute, by mutual consent, valid provisions for such invalid, illegal or unenforceable provisions, which valid provisions best reflect the original intent of the Parties and in their economic effect are sufficiently similar to the invalid, illegal or unenforceable provisions. In the case that such valid provisions cannot be agreed upon, the invalid sentence, paragraph, clause or combination or part of the same shall not affect the validity of this Agreement as a whole and be deleted. The remainder of this Agreement shall remain binding, provided that such deletion does not alter the basic purpose and structure of this Agreement.

17.10 **No Third Party Rights.** Except as expressly this Agreement, no person other than the Parties and their respective Affiliates and permitted assigns shall be deemed an intended Third Party beneficiary hereunder. The Parties do not intend that any term of this Agreement should be enforceable by any person who is not a Party or its respective Affiliates and permitted assigns.

17.11 **Construction.** The Parties mutually acknowledge that they and their attorneys have participated in the negotiation and preparation of this Agreement. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have drafted this Agreement or authorized the ambiguous provision.

17.12 **Interpretation.** The captions and headings to this Agreement are for convenience only, and are to be of no force or effect in construing or interpreting any of the provisions of this

[***] = Certain Confidential Information Omitted

Agreement. Unless context otherwise clearly requires, whenever used in this Agreement: (a) the words “include” or “including” shall be construed as incorporating “but not limited to” or “without limitation”; (b) the words “hereof,” “herein,” “hereby” and derivative or similar words refer to this Agreement, including the Exhibits; (c) all references herein to Sections or Exhibits shall be construed to refer to Sections or Exhibits of this Agreement; (d) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein); (e) the word “notice” means notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement; (f) provisions that require that a Party, the Parties or any committee hereunder “agree”, “consent” or “approve” or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding instant messaging); (g) the words “applicable law”, “applicable laws”, “law” or “laws” means any applicable, legally binding statute, ordinance, resolution, regulation, code, guideline, rule, order, decree, judgment, injunction, mandate or other legally binding requirement of a governmental authority (including a court, tribunal, agency, legislative body or other instrumentality of any (i) government or country or territory, (ii) any state, province, county, city or other political subdivision thereof, or (iii) any supranational body); (h) references to any specific law, rule or regulation, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof; (i) all references to the word “will” are interchangeable with the word “shall” and shall be understood to be imperative or mandatory in nature; (j) all references to “Sublicensees” shall include all Sublicensees through multiple tiers of sublicensing; (k) the singular shall include the plural and vice versa; (l) the word “or” has the inclusive meaning represented by the phrase “and/or”; and (m) all references to days, months, quarters or years are references to calendar days, calendar months, Calendar Quarters, or Calendar Years. This Agreement shall be written and executed in, and all other communications under or in connection with this Agreement the English language. Any translations into any other language shall not be an official version thereof, and event of any conflict in interpretation between the English version and such translation, the English version shall control.

17.13 **Compliance with Laws.** In fulfilling its obligations under this Agreement each Party agrees to comply with all applicable law, statutes, ordinances, codes, rules and regulations.

17.14 **Counterparts.** This Agreement may be executed in two or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. For purposes hereof, a facsimile copy, or email with attached .pdf copy, of this Agreement, including the signature pages hereto, will be deemed to be an original. Notwithstanding the foregoing, the Parties shall deliver original execution copies of this Agreement to one another as soon as practicable following execution thereof.

[Signature page follows – the rest of this page intentionally left blank.]

IN WITNESS WHEREOF, Poseida and Roche have executed this Agreement by their respective officers hereunto duly authorized, on the Execution Date.

POSEIDA THERAPEUTICS, INC.

By: /s/ Mark J.
Gergen
Name: Mark J.
Gergen
Title: President &
CEO

F. HOFFMANN-LA ROCHE LTD

By: /s/ James Sabry
Peter Trybus

Name: James Sabry
Peter Trybus

Title: EVP, Global Head of
Roche
M&A & GF

Partnering, Pharma

By: /s/

Name:

Title: Head Legal

HOFFMANN-LA ROCHE INC.

By: /s/ John
Parise
Name: John
Parise
Title: Authorized
Signatory.

[Signature Page to Collaboration and License Agreement]

Poseida Authorized Subcontractors

[***]

**Exhibit
1.18**

[***] = Certain Confidential Information Omitted
1.18 - 1

[***]

[***] = Certain Confidential Information Omitted
1.18 - 2

Patents within Cas-CLOVER Gene Editing IP existing as of the Execution Date

[***]

[***] = Certain Confidential Information Omitted

[1.29](#) - 1

ED-Go Candidate Success Criteria

[***]

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1.82 - 1

ED Go Data Package

[***]

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1.83 - 1

Excluded Third Party In-License Agreements

[***]

[***] = Certain Confidential Information Omitted

1.88 - 1

Manufacturing Feasibility Criteria for P-BCMA-ALLO1

[***]

**Exhibit
1.138-1**

[***] = Certain Confidential Information Omitted

[1.138-1](#) - 1

[***]

[***] = Certain Confidential Information Omitted

[1.138](#)-1 - 2

Manufacturing Feasibility Criteria for P-CD19/CD20-ALLO1

[***]

**Exhibit
1.138-2**

[***] = Certain Confidential Information Omitted

[1.138-2](#) - 1

[***]

[***] = Certain Confidential Information Omitted

[1.138-2](#) - 2

Exhibit 1.166-1

Phase 1 DE+ Data Package P-BCMA-ALLO1

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[1.166](#) - 3

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[***] = Certain Confidential Information Omitted

[1.166](#) - 4

Exhibit 1.166-2

Phase 1 DE+ Data Package P-CD19CD20-ALLO1

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1.166-2 - 1

[***]

[***] = Certain Confidential Information Omitted

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[***] = Certain Confidential Information Omitted

1.166-2 - 3

[***]

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1.166-2 - 4

Criteria for Technology Transfer Plan

[***]

Exhibit
1.224

[***] = Certain Confidential Information Omitted

1.224 - 1

[***]

[***] = Certain Confidential Information Omitted

1.224 - 2

Patents within Tscm-Enabling IP existing as of the Execution Date

[***]

**Exhibit
1.253**

[***] = Certain Confidential Information Omitted

[1.253](#) - 1

Development Plan for P-BCMA-ALLO1 Tier 1 Program

[***]

**Exhibit
3.1.2-1**

[***] = Certain Confidential Information Omitted

3.4.1-1 - 1

Exhibit 3.1.2-2

Development Plan for P-CD19/CD20-ALLO1 Tier 1 Program

[***]

[***] = Certain Confidential Information Omitted

3.4.1-2 - 1

Initial Collaboration Research Plan

[***]

Exhibit

3.4.1

[***] = Certain Confidential Information Omitted

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3.4.1 - 2

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3.4.1 - 4

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3.4.1 - 5

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3.4.1 - 9

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3.4.1 - 10

Exhibit 6.6.1(a) Study Plan

[***]

[***] = Certain Confidential Information Omitted

[6.6.1\(a\)](#) - 1

[***]

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[6.6.1](#)(a) - 2

Third Party In-License Agreements

[***]

Exhibit 6.10.1

[***] = Certain Confidential Information Omitted

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6.10.1 - 32

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[***] = **Certain Confidential Information Omitted**

6.10.1 - 33

List of Preferred Manufacturers under [***]

[***]

**Exhibit
8.9.2(a)
Reductions
for Third
Party
Payments**

-

[***] = Certain Confidential Information Omitted



Exhibit 11.1
Press Release

Poseida Therapeutics Announces Strategic Global Collaboration with Roche Focused on Allogeneic CAR-T Cell Therapies for Hematologic Malignancies

Leveraging Poseida's novel approach to cell therapy and Roche's expertise in developing and commercializing therapies to transform cancer care, the collaboration is focused on advancing multiple existing and additional next generation allogeneic CAR-T programs directed to hematologic malignancies

Poseida will receive \$110 million upfront, could receive up to \$110 million in near-term milestones and other payments, and is eligible for future development and commercial milestones and tiered royalty payments

Poseida to host a brief conference call today at 8:30 a.m. ET

SAN DIEGO, [August 3], 2022 – Poseida Therapeutics, Inc. (Nasdaq: PSTX), a clinical-stage biopharmaceutical company utilizing proprietary genetic engineering platform technologies to create cell and gene therapeutics with the capacity to cure, today announced it has entered into a broad strategic collaboration and license agreement with Roche, focused on developing allogeneic CAR-T therapies directed to hematologic malignancies. The global collaboration covers the research and development of multiple existing and novel “off-the- shelf” cell therapies against targets in multiple myeloma, B-cell lymphomas and other hematologic indications.

“We are excited to partner and collaborate with Roche, one of the world’s largest biotechnology companies, which has a successful track record in the discovery, development and commercialization of innovative medicines,” said Mark Gergen, Chief Executive Officer of Poseida. “Roche is an ideal strategic partner for Poseida with its industry-leading R&D capabilities in oncology, complementary technologies and expertise, and global regulatory and commercial capabilities. Working together, we look forward to advancing novel allogeneic cell therapies based upon Poseida’s technologies for patients battling cancer.” Under the agreement, Roche will receive from Poseida either exclusive rights or options to develop and commercialize a number of allogeneic CAR-T programs in Poseida’s portfolio that are directed to hematologic malignancies, including P-BCMA-ALLO1, an allogeneic CAR- T for the treatment of multiple myeloma and for which a Phase 1 study is underway, and P- CD19CD20-ALLO1, an allogeneic dual CAR-T for the treatment of B-cell malignancies with an IND expected in 2023. Building on complementary expertise and capabilities, the parties will also collaborate in a research program to create and develop next-generation features and improvements for allogeneic CAR-T therapies, from which they would jointly develop additional allogeneic CAR-T product candidates directed to existing and new hematologic targets. For a subset of both the Poseida portfolio programs licensed or optioned to Roche and the parties’ future collaboration programs, Poseida will conduct the Phase 1 studies and manufacture clinical materials before transitioning the programs to Roche for further development and commercialization. Roche will be solely responsible for the late-stage

clinical development and global commercialization of all products that are subject to the collaboration.

“We are excited to partner with Poseida to further explore the potential of allogeneic cell therapies to transform cancer care by developing off-the-shelf products that can address high unmet medical needs for a broad patient population,” said James Sabry, Global Head of Pharma Partnering at Roche. “Poseida’s differentiated platform technologies complement our ongoing internal efforts and partnerships to discover and develop cell therapies as a next generation of medicines for patients.”

Under the agreement, Poseida will receive \$110 million upfront and could receive up to \$110 million in near-term milestones and other payments in the next several years. In addition, Poseida is eligible to receive research, development, launch, and net sales milestones and other payments potentially up to \$6 billion in aggregate value, as well as tiered net sales royalties into the low double digits, across multiple programs.

“We are thrilled that Roche has embraced the opportunity to partner with us and use Poseida’s unique allogeneic approach to develop CAR-T product candidates,” said Devon J. Shedlock, Ph.D., Chief Scientific Officer, Cell Therapy at Poseida. “Using our proprietary technologies and manufacturing process including our booster molecule, we have the potential to develop and manufacture a product with high levels of stem cell memory T cells, which are correlated with potent antitumor efficacy in the clinic, at a scale that can potentially reach more patients and enable broad commercial use.”

The effectiveness of the agreement is subject to clearance under the Hart-Scott-Rodino Antitrust Improvements Act (HSR Act).

Poseida Therapeutics Conference Call and Webcast Information

Wednesday, August 3, 2022 at 8:30 a.m. ET

Poseida's management team will host a conference call and webcast today at 8:30 a.m. ET to discuss the collaboration and Poseida’s novel approach to allogeneic cell therapy. The dial- in numbers for domestic and international callers are 800-267-6316 and 203-518-9814, respectively. The conference ID number for the call is PSTX0803.

Participants may access the live webcast on the Investors & Media Section of the Poseida website, www.poseida.com. An archived replay of the webcast will be available for approximately 30 days following the event.

About Poseida Therapeutics, Inc.

Poseida Therapeutics is 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 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. To learn more, visit www.poseida.com and connect with us on [Twitter](#) and [LinkedIn](#).

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include statements regarding, among other things, the upfront payment and other potential fees, milestone and royalty payments and development activities under the collaboration agreement, the potential benefits of Poseida's technology platforms and product candidates, the clearance of the collaboration agreement under the HSR Act, Poseida's plans and strategy with respect to developing its technologies and product candidates, and anticipated timelines and milestones with respect to Poseida's development programs and manufacturing activities. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. These forward-looking statements are based upon Poseida's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, the fact that the collaboration agreement may not become effective based on HSR Act clearance, or the effectiveness may be substantially delayed, or may be terminated early, the fact that the Company will have limited control over the efforts and resources that Roche devotes to advancing development programs under the collaboration agreement and Poseida may not receive the potential fees and payments under the collaboration agreement or fully realize the benefits of the collaboration, risks and uncertainties associated with development and regulatory approval of novel product candidates in the biopharmaceutical industry, the fact that future preclinical and clinical results could be inconsistent with results observed to date, and the other risks described in Poseida's filings with the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. Poseida undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

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Exhibit 13.2.4 Encumbrances

[***]

[***] = Certain Confidential Information Omitted

**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: November 10, 2022

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

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

I, 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: November 10, 2022

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

**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 September 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: November 10, 2022

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

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

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 September 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: November 10, 2022

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