UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended September 30, 2023
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: 001-41259

ARCELLX, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**47-2855917**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
25 West Watkins Mill Road, Suite A Gaithersburg, MD	**20878**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (240) 327-0603

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.001 par value per share	ACLX	The Nasdaq Global Select Market

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

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

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

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

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

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

As of November 9, 2023, the registrant had 48,686,187 shares of common stock, $0.001 par value per share, outstanding.

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"Arcellx," "we," "us," "our," or "the Company" as used in this Quarterly Report on Form 10-Q refer to Arcellx, Inc. and, where appropriate, our subsidiary, Subdomain, LLC.

Special Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q (Quarterly Report) contains express or implied forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act), that are based on our management's belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by these forward-looking statements. Forward-looking statements in this Quarterly Report include, but are not limited to, statements about:

- the ability of our clinical trials to demonstrate safety and efficacy of our product candidates, and other favorable results;
- our plans relating to the clinical development of our product candidates, including the disease areas to be evaluated;
- the timing, progress, and results of preclinical studies and clinical trials for our programs and product candidates, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, and our research and development programs;
- our ability to recruit and enroll suitable patients in our clinical trials;
- our expectations that the risk mitigation strategies implemented during the partial clinical hold on the iMMagine-1 trial, including modifications to the protocol and additional efforts will mitigate additional serious adverse events in the trial;
- our ability to take advantage of expedited regulatory pathways for our product candidates;
- our plans relating to commercializing our product candidates, if approved, including the geographic areas of focus and sales strategy;
- our ability to maintain our collaborative relationship with Kite in connection with the development, manufacturing and commercialization of certain of our product candidates;
- the expected benefits of potential strategic collaborations with third parties, including our collaboration with Kite and our ability to attract additional collaborators with development, regulatory and commercialization expertise;
- the size of the market opportunity for our product candidates and our ability to maximize those opportunities;
- the success of competing therapies that are or may become available;
- our estimates of the number of patients who suffer from the diseases we are targeting and the number of participants that will enroll in our clinical trials;
- the beneficial characteristics, safety, efficacy and therapeutic effects of our product candidates;
- the timing or likelihood of regulatory filings and approvals, including our expectation to seek special designations, such as orphan drug designation, for our product candidates for various diseases;
- our ability to obtain and maintain regulatory approval of our product candidates;
- our ability to adequately secure our information technology systems and the regulated data stored therein, as required by law;
- the pricing and reimbursement of our product candidates, if approved;

•our plans relating to the further development and manufacturing of our product candidates, including for additional indications that we may pursue;

•existing regulations and regulatory developments in the United States and other jurisdictions;

•our plans and ability to obtain or protect intellectual property rights, including extensions of existing patent terms where available;

•our reliance on third parties to conduct clinical trials of our product candidates and manufacture of our product candidates for preclinical studies and clinical trials;

•the need to hire additional personnel and our ability to attract and retain such personnel;

•the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;

•our financial performance;

•the sufficiency of our existing cash and cash equivalents and marketable securities to fund our future operating expenses and capital expenditure requirements;

•the impact of global economic and political developments on our business, including rising inflation and capital market disruptions, military conflicts in Ukraine, Israel, and the Middle East, economic sanctions and economic slowdowns or recessions that may result from such developments which could harm our research and development efforts as well as the value of our common stock and our ability to access capital markets;

•the lasting impact of the COVID-19 pandemic or other related disruptions on our business; and

•our anticipated use of our existing resources.

Forward-looking statements are not historical facts, but rather are based on current expectations, estimates, assumptions, and projections about the business and future financial results of the pharmaceutical industry, and other legal, regulatory, and economic developments. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “intend,” “should,” “could,” “would,” “expect,” “plan,” “anticipate,” “believe,” “estimate,” “project,” “predict,” “potential,” “continue,” “likely,” and similar expressions (including their use in the negative) intended to identify forward-looking statements although not all forward-looking statements contain these identifying words. Actual results could differ materially from the results contemplated by these forward-looking statements due to a number of factors, including, but not limited to, those described in Part II, Item 1A (Risk Factors) of this Quarterly Report.

You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, which are, in some cases, beyond our control and which could materially affect results. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance. You should read this Quarterly Report and the documents that we reference in this Quarterly Report and have filed with or furnished to the U.S. Securities and Exchange Commission (the SEC) completely and with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements.

The forward-looking statements in this Quarterly Report represent our views as of the date of this Quarterly Report. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Quarterly Report.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

ARCELLX, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)
(in thousands, except share and per share amounts)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 126,119	$ 64,179
Marketable securities	313,597	190,656
Receivable from collaboration partner	31,480	—
Prepaid expenses and other current assets	20,260	12,028
Total current assets	491,456	266,863
Restricted cash	4,929	2,501
Property and equipment, net	37,782	11,231
Operating lease right-of-use assets	29,142	28,659
Marketable securities non current	42,960	—
Prepaid research and development expenses and other long-term assets	7,949	4,563
Total assets	$ 614,218	$ 313,817
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 7,185	$ 9,053
Accrued liabilities	16,916	11,679
Contract liability	94,180	—
Operating lease liabilities, current portion	6,582	2,901
Finance lease liabilities, current portion	48,286	33,060
Total current liabilities	173,149	56,693
Operating lease liabilities, net of current portion	48,096	31,299
Finance lease liabilities, net of current portion	5,755	20,871
Contract liability, net of current portion	121,090	—
Total liabilities	348,090	108,863
Commitments and contingencies (Note 7)		
Stockholders' equity		
Preferred stock, par value of $0.001 per share; 200,000,000 shares authorized and no shares issued and outstanding as of September 30, 2023 or December 31, 2022	—	—
Common stock, par value of $0.001 per share; 1,000,000,000 shares authorized and 48,673,675 shares issued and outstanding as of September 30, 2023; 1,000,000,000 shares authorized and 44,105,981 shares issued and outstanding as of December 31, 2022	48	44
Additional paid-in capital	675,469	523,921
Accumulated other comprehensive loss	(65)	(221)
Accumulated deficit	(409,324)	(318,790)
Total stockholders' equity	266,128	204,954
Total liabilities and stockholders' equity	$ 614,218	$ 313,817

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

ARCELLX, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Collaboration revenue	$ 14,957	$ —	$ 47,171	$ —
Operating expenses:				
Research and development	43,807	83,473	105,065	123,612
General and administrative	16,012	10,402	46,985	27,643
Total operating expenses	59,819	93,875	152,050	151,255
Loss from operations	(44,862)	(93,875)	(104,879)	(151,255)
Other income (expense):				
Interest income, net	6,479	1,597	17,251	2,172
Interest expense	(959)	(596)	(2,865)	(604)
Total other income, net	5,520	1,001	14,386	1,568
Loss before income taxes	(39,342)	(92,874)	(90,493)	(149,687)
Income tax (expense) benefit	6	—	(41)	—
Net loss	(39,336)	(92,874)	(90,534)	(149,687)
Other comprehensive loss:				
Unrealized gain (loss) on marketable securities	(58)	(137)	156	(379)
Comprehensive loss	$ (39,394)	$ (93,011)	$ (90,378)	$ (150,066)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.81)	$ (2.12)	$ (1.89)	$ (4.43)
Weighted-average common shares outstanding—basic and diluted	48,438,094	43,819,365	47,777,446	33,814,418

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

ARCELLX, INC.
CONDENSED CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(unaudited)
(in thousands, except share data)

	Common Stock		Stockholders' Equity			
	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Gain (Loss)	Stockholders' Equity
Balance as of December 31, 2022	44,105,981	$ 44	$ 523,921	$ (318,790)	$ (221)	$ 204,954
Issuance of common stock in accordance with Gilead Stock Purchase Agreement	3,478,261	4	115,266	—	—	115,270
Exercise of stock options	34,713	—	374	—	—	374
Issuance of common stock from vesting of restricted stock	222,433	—	—	—	—	—
Share-based compensation	—	—	10,156	—	—	10,156
Unrealized gain on marketable securities	—	—	—	—	307	307
Net loss	—	—	—	(27,344)	—	(27,344)
Balance as of March 31, 2023	47,841,388	$ 48	$ 649,717	$ (346,134)	$ 86	$ 303,717
Exercise of stock options	398,861	—	2,965	—	—	2,965
Issuance of common stock from vesting of restricted stock	46,593	—	—	—	—	—
Issuance of common stock pursuant to employee stock purchase plan	28,549	—	528	—	—	528
Share-based compensation	—	—	10,404	—	—	10,404
Unrealized loss on marketable securities	—	—	—	—	(93)	(93)
Net loss	—	—	—	(23,854)	—	(23,854)
Balance as of June 30, 2023	48,315,391	$ 48	$ 663,614	$ (369,988)	$ (7)	$ 293,667
Exercise of stock options	343,263	—	1,241	—	—	1,241
Issuance of common stock from vesting of restricted stock	15,021	—	—	—	—	—
Share-based compensation	—	—	10,614	—	—	10,614
Unrealized loss on marketable securities	—	—	—	—	(58)	(58)
Net loss	—	—	—	(39,336)	—	(39,336)
Balance as of September 30, 2023	48,673,675	$ 48	$ 675,469	$ (409,324)	$ (65)	$ 266,128

	Redeemable Convertible Preferred Stock						Stockholders' Equity (Deficit)					
	Series A		Series B		Series C		Common Stock					
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive (Loss)	Stockholders' Equity (Deficit)
Balance as of December 31, 2021	5,413,272	$ 28,894	8,975,585	$ 85,367	10,396,707	$ 119,118	544,210	$ 1	$ 8,615	$ (130,111)	$ (20)	$ (121,515)
Issuance of common stock (initial public offering),net of transaction costs of $15,029	—	—	—	—	—	—	9,487,500	9	127,274	—	—	127,283
Issuance of common stock (private placement), net of transaction costs of $42	—	—	—	—	—	—	590,318	1	9,957	—	—	9,958
Conversion of preferred stock to common stock	(5,413,272)	(28,894)	(8,975,585)	(85,367)	(10,396,707)	(119,118)	24,785,564	25	233,354	—	—	233,379
Issuance of common stock from vesting of restricted stock	—	—	—	—	—	—	24,889	—	107	—	—	107
Exercise of stock options	—	—	—	—	—	—	286,283	—	307	—	—	307
Share-based compensation	—	—	—	—	—	—	—	—	4,481	—	—	4,481
Unrealized loss on marketable securities	—	—	—	—	—	—	—	—	—	—	(24)	(24)
Net loss	—	—	—	—	—	—	—	—	—	(26,041)	—	(26,041)
Balance as of March 31, 2022	—	$ —	—	$ —	—	$ —	35,718,764	$ 36	$ 384,095	$ (156,152)	$ (44)	$ 227,935
Issuance of common stock (follow-on offering), net of transaction costs of $8,081	—	—	—	—	—	—	8,050,000	8	120,711	—	—	120,719
Issuance of common stock from vesting of restricted stock	—	—	—	—	—	—	13,294	—	11	—	—	11
Exercise of stock options	—	—	—	—	—	—	—	—	—	—	—	—
Share-based compensation	—	—	—	—	—	—	—	—	5,944	—	—	5,944
Unrealized loss on marketable securities	—	—	—	—	—	—	—	—	—	—	(218)	(218)
Net loss	—	—	—	—	—	—	—	—	—	(30,772)	—	(30,772)
Balance as of June 30, 2022	—	$ —	—	$ —	—	$ —	43,782,058	$ 44	$ 510,761	$ (186,924)	$ (262)	$ 323,619
Issuance of common stock from vesting of restricted stock	—	—	—	—	—	—	4,526	—	4	—	—	4
Exercise of stock options	—	—	—	—	—	—	59,809	—	343	—	—	343
Share-based compensation	—	—	—	—	—	—	—	—	5,329	—	—	5,329
Unrealized loss on marketable securities	—	—	—	—	—	—	—	—	—	—	(137)	(137)
Net loss	—	—	—	—	—	—	—	—	—	(92,874)	—	(92,874)
Balance as of September 30, 2022	—	$ —	—	$ —	—	$ —	43,846,393	$ 44	$ 516,437	$ (279,798)	$ (399)	$ 236,284

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

ARCELLX, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)
(in thousands)

	Nine Months Ended September 30, 2023	2022
Cash flows from operating activities		
Net loss	$ (90,534)	$ (149,687)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,318	905
Noncash operating lease expense	813	1,188
Right-of-use asset expensed	18,247	63,148
Amortization of premiums and discounts on marketable securities	(7,104)	(768)
Share-based compensation	31,174	15,754
Changes in operating assets and liabilities:		
Receivable from collaboration partner	(31,480)	—
Prepaid expenses and other current and non-current assets	(14,991)	(4,150)
Accounts payable and other current liabilities	(1,648)	1,494
Accrued liabilities	(1,420)	(677)
Operating lease liabilities	13,883	1,010
Contract liability	231,067	—
Net cash provided by (used in) operating activities	149,325	(71,783)
Cash flows from investing activities		
Purchases of property and equipment	(16,135)	(1,001)
Purchases of marketable securities	(400,044)	(247,980)
Proceeds from maturities of marketable securities	240,650	97,685
Net cash used in investing activities	(175,529)	(151,296)
Cash flows from financing activities		
Proceeds from issuance of common stock in accordance with Gilead Stock Purchase Agreement	100,000	—
Proceeds from issuance of common stock (initial public offering), net of transactions costs	—	129,156
Proceeds from issuance of common stock (private placement), net of transactions costs	—	9,958
Proceeds from issuance of common stock (follow-on offering), net of transactions costs	—	120,719
Proceeds from exercise of stock options	4,582	773
Payments under finance leases	(14,010)	(9,295)
Net cash provided by financing activities	90,572	251,311
Net increase in cash and cash equivalents and restricted cash	64,368	28,232
Cash and cash equivalents and restricted cash, beginning of the year	66,680	31,032
Cash and cash equivalents and restricted cash, end of the period	$ 131,048	$ 59,264
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	$ 212	$ —
Supplemental disclosures of noncash investing and financing activities:		
Purchase of property and equipment included in accounts payable and accrued liabilities	$ 7,206	$ 430

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

1. Nature of the Business

Organization

Arcellx, Inc. (Arcellx or the Company) was incorporated in Delaware in December 2014 and is headquartered in Gaithersburg, Maryland. The Company is a clinical-stage biopharmaceutical company reimagining cell therapy through the development of innovative therapies for patients with cancer and other incurable diseases.

Liquidity

The Company has incurred significant operating losses since inception and has an accumulated deficit of $409.3 million as of September 30, 2023. The Company has relied on its ability to fund its operations through private and public equity financings and its recent collaboration and license agreement with Kite Pharma, Inc (Kite), a Gilead Sciences, Inc. (Gilead) company. In January 2023, the Company received in the aggregate $325.0 million in cash which consisted of $100.0 million related to a private placement from the sale of the Company's common stock to Gilead and a $225.0 million non-refundable, upfront payment related to the closing of its Collaboration and License Agreement (Kite Collaboration Agreement) with Kite. See Note 6 Collaboration Agreement.

As of September 30, 2023, the Company had $ 482.7 million of cash, cash equivalents and marketable securities, which management believes will be sufficient to meet the Company's anticipated operating and capital expenditure requirements for at least twelve months following the date of issuance of these financial statements.

2. Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP) for interim financial information and the related rules and regulations of the Securities and Exchange Commission (SEC). Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. In the Company's opinion, all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair presentation of the results of operations and cash flows for the periods presented have been included.

Operating results for the three and nine months ended September 30, 2023 are not necessarily indicative of the results that may be expected for the year ending December 31, 2023 or for any future period. The balance sheet as of December 31, 2022 has been derived from audited consolidated financial statements at that date but does not include all of the information required by U.S. GAAP for complete financial statements.

The accompanying unaudited condensed consolidated financial statements and related financial information should be read in conjunction with the audited consolidated financial statements and the related notes thereto as of and for the year ended December 31, 2022 included in the Company's Annual Report on Form 10-K filed with the SEC on March 29, 2023.

The accompanying condensed consolidated financial statements include the accounts of Arcellx, Inc. and its wholly-owned subsidiary. All intercompany balances and transactions have been eliminated in consolidation.

Emerging Growth Company and Smaller Reporting Company Status

The Company is an emerging growth company (EGC), as defined in the Jumpstart Our Business Startups Act of 2012 (JOBS Act). Under the JOBS Act, companies have extended transition periods available for complying with new or revised accounting standards. The Company has elected this exemption to delay adopting new or revised accounting standards until such time as those standards apply.

On the last business day of the second quarter in 2023, the aggregate market value of the Company's shares of common stock held by non-affiliate stockholders exceeded $700 million. As a result, as of December 31, 2023, the Company will be considered a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, and will cease to be an EGC. Due to loss of EGC status, the Company will no longer be exempt from the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, and our independent registered public accounting firm will evaluate and report on the effectiveness of internal control over financial reporting.

Commencing with the Company's Annual Report on Form 10-K for the year ending December 31, 2023, the Company will adopt any accounting pronouncements deferred under the extended transition period election on or before December 31, 2023.

Effective December 31, 2023, due to large accelerated filer status, the Company will also no longer be permitted to take advantage of reduced reporting requirements for smaller reporting companies, subject to a transition period that allows for the Company to use smaller reporting company scaled disclosure for the Company's Annual Report on Form 10-K for the year ending December 31, 2023.

Use of Accounting Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates used in preparing the accompanying condensed consolidated financial statements include, but are not limited to, estimates related to the fair value of assets, collaboration revenue, research and development accruals, recoverability of long-lived assets, share-based compensation, and income taxes. Although actual results could differ from those estimates, management does not believe that such differences would be material.

Cash and Cash Equivalents and Restricted Cash

The Company considers all highly liquid investments with an original maturity of three months or less at the date of purchase to be cash equivalents. The Company deposits its cash primarily in checking and sweep accounts with commercial banks and financial institutions in amounts exceeding FDIC insurance limits. Cash equivalents consist of money market funds.

The Company is required to maintain cash collateral on deposit in segregated money market bank accounts as a condition of its lease agreements on its properties, equal to the required security deposit amounts. These amounts, together with restricted cash at September 30, 2023 and 2022 representing cash balances are presented as non-current restricted cash on the Company's consolidated balance sheets.

The following table provides a reconciliation of cash, cash equivalents and restricted cash within the condensed consolidated balance sheets to the total shown in the condensed consolidated statements of cash flows (in thousands):

	September 30,	
	2023	**2022**
Cash and cash equivalents	$ 126,119	$ 56,763
Restricted cash	4,929	2,501
Total	$ 131,048	$ 59,264

Marketable Securities

Securities are classified at the time of purchase, based on management's intention, as debt securities held-to-maturity, debt securities available-for-sale, trading account securities or equity securities. Debt securities held-to-maturity are those that management has the positive intent and ability to hold until maturity. Debt securities held-to-maturity are carried at amortized cost, adjusted for amortization of premiums and accretion of discounts using the level-yield method over the contractual term of the securities, adjusted for actual prepayments. Debt securities available-for-sale represent all securities not classified as either held-to-maturity, trading, or equity. Debt securities available-for-sale are carried at estimated fair value with unrealized holding gains and losses (net of related tax effects) on such securities excluded from earnings, but included as a separate component of stockholders' equity, titled "Accumulated other comprehensive income (loss)." The cost of securities sold is determined using the specific-identification method. Security transactions are recorded on a trade-date basis.

For securities available for sale, ASU 2016-13 eliminates the concept of other-than-temporary impairment and instead requires entities to determine if impairment is related to credit loss or non-credit loss. In making the assessment of whether a loss is from credit or other factors, management considers the extent to which fair value is less than amortized cost, any changes to the rating of the security by a rating agency and adverse conditions related to the security, among other factors. If this assessment indicates that a credit loss exists, the present value of cash flows expected to be collected from the security are compared to the amortized cost basis of the security. If the present value of cash flows is less than the amortized cost basis, a credit loss exists and an allowance is created, limited by the amount that the fair value is less than the amortized cost basis. Subsequent activity related to the credit loss component in the form of write-offs or recoveries is recognized as part of the allowance for credit losses on securities available for sale.

Management measures expected credit losses on held-to-maturity debt securities on a collective basis by major security type. Our held-to-maturity securities in the Company's portfolio are either issued by U.S. government agencies or are highly rated short term corporate bonds; U.S government agency bonds are either explicitly or implicitly guaranteed by the U.S government. The Company's investment in short-term bonds is in a net gain position and the expectation is that any unrecognized losses will be recovered by maturity; therefore, the expectation of nonpayment is zero.

Prior to the adoption of ASU 2016-13 on January 1, 2023, the Company's evaluation of other-than-temporary impairment considered management's assessment of the reason for the decline in value, the duration and severity of the impairment, management's intent and ability to hold the securities (as well as the likelihood of a near-term recovery), and management's intent to sell the securities and whether it was more likely than not that the Company would be required to sell the securities before the recovery of their amortized cost basis. If a determination was made that a debt security was other-than-temporarily impaired, the Company would estimate the amount of the unrealized loss that was attributable to credit and all other non-credit related factors. If the Company intended to hold securities in an unrealized loss position until the loss was recovered, which may be at maturity, the credit related component was recognized as an other-than-temporary impairment charge in non-interest income. The non-credit related component was recorded as an adjustment to accumulated other comprehensive income (loss), net of tax.

The Company has made the accounting policy election to exclude accrued interest receivable on securities from the estimate of credit losses. Accrued interest receivable totaled $1.7 million and $0.5 million at September 30, 2023 and December 31, 2022, respectively and is included in prepaid expenses and other current assets in the condensed consolidated balance sheets.

Concentration of Credit Risk

Financial instruments that potentially expose the Company to concentrations of credit risk primarily consist of cash and cash equivalents, restricted cash, marketable securities and receivables from collaboration partner. The Company maintains its cash and cash equivalents and restricted cash at an accredited financial institution in amounts that exceed federally insured limits. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships. The Company invests in highly rated debt securities consisting entirely of corporate and government bonds, which the Company has the ability to liquidate within one-day should the need for additional cash arise. Accordingly, the Company believes the exposure to credit risk on its marketable securities portfolio is low. The Company's receivable from collaboration partner consists of short-term receivables from a well-capitalized public company; accordingly the Company believes the exposure to credit risk on its receivable from collaboration partner is low.

Recently Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13 "Financial Instruments - Credit Losses" ("ASC 326"): Measurement of Credit Losses on Financial Instruments" which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. ASU 2016-13 replaces the existing incurred loss impairment model with an expected loss model which requires the use of forward-looking information to calculate credit loss estimates. It also eliminates the concept of other-than-temporary impairment and requires credit losses related to available-for-sale debt securities to be recorded through an allowance for credit losses rather than as a reduction in the amortized cost basis of the securities. These changes will result in earlier recognition of credit losses. In November 2019, the FASB issued ASU 2019-10 "Financial Instruments - Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842)" ("ASC 2019-10"), which defers the effective date of ASU 2016-13 to fiscal years beginning after December 15, 2022, including interim periods within those fiscal years, for public entities which meet the definition of a smaller reporting company. The Company adopted ASU 2016-13 effective January 1, 2023 and there was no effect on the Company's condensed consolidated financial statements.

Collaborative Arrangements and Contracts with Customers

The Company assesses whether its collaboration agreements are subject to Accounting Standards Codification (ASC) Topic 808, Collaborative Arrangements (ASC 808) based on whether they involve joint operating activities and whether both parties have active participation in the arrangement and are exposed to significant risks and rewards that depend on the commercial success of the joint operating activities. To the extent that the arrangement falls within the scope of ASC 808, the Company applies the unit of account guidance under ASC Topic 606, Revenue from Contracts with Customers (ASC 606), to identify distinct performance obligations, and then determine whether a customer relationship exists for each distinct performance obligation. If the Company determines whether a promised good or service within the arrangement is with a customer, it applies the guidance in ASC 606. If a portion of a distinct bundle of goods or services within an arrangement is not with a customer, then the unit of account is not within the scope of ASC 606, and the recognition and measurement of that unit of account shall be based on analogy to authoritative accounting literature or, if there is no appropriate analogy, a reasonable, rational, and consistently applied accounting policy election.

The Company recognizes revenue when its customer obtains control of promised goods or services in a contract for an amount that reflects the consideration the Company expects to receive in exchange for those goods or services. For contracts with customers, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies each performance obligation. The Company only applies the five-step model to contracts when it is probable that Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. As part of the accounting for contracts with customers, the Company must develop assumptions that require judgment to determine the standalone selling price of each performance obligation identified in the contract. The Company then allocates the total transaction price to each performance obligation based on their estimated standalone selling prices. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

If the consideration promised in a contract includes a variable amount, the Company estimates the amount of consideration to which it will be entitled in exchange for transferring the promised goods or services to a customer. The Company determines the amount of variable consideration by using the expected value method or the most likely amount method. The Company includes the unconstrained amount of estimated variable consideration in the transaction price. The amount included in the transaction price is the amount for which it is probable that a significant reversal of cumulative revenue recognized will not occur. At the end of each subsequent reporting period, the Company re-evaluates the estimate of variable consideration included in the transaction price and any related constraint, and if necessary, adjusts the estimate of the overall transaction price. Variable consideration, such as milestone payments and consideration paid or payable to a collaboration partner, must be evaluated to determine if it is constrained and, therefore, excluded from the transaction price. Any such adjustments are recorded on a cumulative catch-up basis in the period of adjustment.

The accounting for these arrangements requires the Company to develop estimates and assumptions that require judgment to determine the underlying stand-alone selling price for each performance obligation, which determines how the transaction price is allocated among the performance obligations. These estimates may include items such as forecasted revenues or costs, development timelines, discount rates, and probabilities of technical and regulatory success. The Company evaluates each performance obligation to determine if it is satisfied at a point in time or over time. For performance obligations satisfied over time, the Company determines the appropriate measure of progress. The effect of any change made to the measure of progress and, therefore a change to revenue, would be recorded as a change in estimate.

The Company's collaborative arrangements can have one or more of the following forms of consideration: (i) license fees; (ii) milestone payments related to the achievement of developmental, regulatory, or commercial goals; (iii) royalties on net sales of licensed products; (iv) fees attributable to options to intellectual property; (v) cost-sharing or research and development (R&D) funding arrangements and (vi) profit and loss sharing. When a portion of non-refundable upfront fees or other payments received are allocated to continuing performance obligations under the terms of a collaborative arrangement, they are recorded as contract liabilities and recognized as revenue when (or as) the underlying performance obligation is satisfied. The Company classifies contract liabilities as current when it expects to satisfy its performance obligations within one year, and noncurrent when the Company expects to satisfy those performance obligations in greater than one year. Fees attributable to options are deferred until the option expires or is exercised. Changes to collaboration agreements are assessed for whether they represent a modification or should be accounted for as a new contract.

Upfront Payments and License Fees

If a license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from non-refundable, upfront fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Variable Consideration

Variable consideration is assessed at each reporting period as to whether it is not subject to future reversal of cumulative revenue and, therefore, should be included in the transaction price. Assessing the recognition of variable consideration requires judgment. Consideration paid or payable to a collaboration partner is estimated and included in the total transaction price. Variable consideration is included in the transaction price when the Company concludes that it is probable that a significant revenue reversal will not occur in future periods. Actual amounts of consideration ultimately received may differ from the Company's estimates.

Cost-sharing

Under certain collaborative arrangements, the Company can be reimbursed for a portion of its research and development expenses or reimburse its collaboration partner for its research and development expenses. The Company estimates reimbursements to be received by a collaboration partner and reimbursements to be paid or payable to a collaboration partner as part of variable consideration. When these research and development services are paid to a collaboration partner, the Company reduces its contract liability.

Customer Options

Customer options, such as options granted to allow a licensee to extend a license or research term, to select additional research targets or to choose to research, develop and commercialize licensed compounds are evaluated at contract inception to determine whether those options provide a material right (i.e., an optional good or service offered for free or at a discount) to the customer. If the customer options represent a material right, the material right is treated as a separate performance obligation at the outset of the arrangement. The Company allocates the transaction price to material rights based on the standalone selling price. As a practical alternative to estimating the standalone selling price of a material right when the underlying goods or services are both (i) similar to the original goods or services in the contract and (ii) provided in accordance with the terms of the original contract, the Company allocates the total amount of consideration expected to be received from the customer to the total goods or services expected to be provided to the customer. Amounts allocated to any material right are recognized as revenue when or as the related future goods or services are transferred or when the option expires.

Milestone Payments

At the inception of the arrangement, the Company evaluates whether the development or sales-based milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated value is included in the transaction price. Milestone payments that are not within the control of the Company or the Company's collaboration partner, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development or sales-based milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues in the period of adjustment.

The Company may earn milestones through achievement of pre-specified developmental or regulatory events and, as such, milestones are accounted for as variable consideration. Under the agreement currently in place, the Company does not consider these events to be within its control, but rather dependent upon the development activities of our collaborative partner and the decisions made by regulatory agencies. Accordingly, these milestones are not included in the transaction price until the counterparty, or third-party in the event of a regulatory submission, confirms the satisfaction or completion of the milestone triggering event. Given the high level of uncertainty of achievement, variable consideration associated with milestones are fully constrained. The value of these milestones is dictated within the contract and is fixed upon achievement and reflects the amount of consideration which the Company expects to be entitled in exchange for the satisfaction of that milestone. The process of successfully discovering a new development candidate, having it approved and successfully commercialized is highly uncertain. As such, the milestone payments we may earn from the Company's partners involve a significant degree of risk to achieve and therefore, subsequent milestone payments due to the Company are recognized as revenue at the point in time when such milestones are achieved. For milestone revenues related to sales-based achievements, the Company recognizes the milestone revenues in the corresponding period of the product sale, in accordance with the guidance of ASC 606-10-55-65 for contracts that include a license to intellectual property and the license is the predominant item to which the product sale relates.

Royalties

For arrangements that include sales-based royalties, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue resulting from its collaborative arrangement.

The timing of revenue recognition and contract billings may differ and result in contract assets and contract liabilities. Contract assets represent revenues recognized in excess of amounts billed under collaboration agreements and are transferred to accounts receivable when billed or billing rights become unconditional. Contract liabilities represent billings in excess of revenues recognized under collaboration agreements.

Leases

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). Topic 842 increases transparency and comparability among organizations by requiring the recognition of lease assets and lease liabilities on the balance sheet and disclosure of key information about leasing arrangements for both lessees and lessors. The Company adopted the new standard effective January 1, 2022, electing to use the package of practical expedients permitted under the transition guidance which allows for the carry forward of historical lease classification for existing leases on the adoption date and does not require the assessment of existing lease contracts to determine whether the contracts contain a lease or initial direct costs. The Company also elected the practical expedient to not separate non-lease components from lease components and instead to account for each separate lease component and the non-lease components associated with that lease component as a single lease component for leases associated with office and laboratory space, manufacturing facilities, and equipment. Prior periods were not retrospectively adjusted.

The adoption of this standard resulted in the recognition of operating lease right-of-use (ROU) assets in the amount of $3.3 million and operating lease liabilities in the amount of $5.4 million on the consolidated balance sheet, with a $2.1 million reclassification of deferred rent and tenant improvement allowances. There was no cumulative effect adjustment to the opening balance of accumulated deficit as of January 1, 2022. The adoption of this standard did not have an impact on the consolidated statements of operations or cash flows on the effective date.

The Company leases office and laboratory space and equipment. In addition, the Company enters into manufacturing supply agreements with CMOs and CDMOs to manufacture clinical product candidate materials. Such agreements may include an embedded lease due to the exclusive use of identified manufacturing facilities and equipment that are controlled by the Company and for which the Company obtains substantially all the output. The evaluation of leases that are embedded in the Company's CMO and CDMO agreements is complex and requires judgment. If a lease arrangement is determined to exist with a lease term of more than 12 months at the lease commencement date, an ROU asset and corresponding lease liability are recorded on the consolidated balance sheet at the lease commencement date based on the present value of fixed lease payments over the lease term. The lease commencement date, defined as the date on which the lessor makes the underlying asset available for use by the lessee and the date from which the Company is required to recognize lease expenses, may be different from the inception date of the contract.

An ROU asset represents the right to control the use of an identified asset over the lease term and a lease liability represents the obligation to make lease payments arising from the lease. The Company uses the discount rate implicit in the lease, if available, or its incremental borrowing rate on the lease commencement date to determine the present value of lease payments. The lease terms used to calculate the ROU assets and related lease liabilities include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. The Company expenses ROU assets acquired for research and development activities under ASC Topic 730, Research and Development, if they do not have alternative future use, in research and development projects or otherwise.

Leases are classified as either operating or finance leases based on the economic substance of the agreement. For operating leases, the Company recognizes lease expense related to fixed payments on a straight-line basis over the lease term. For finance leases, the Company recognizes the amortization of the ROU asset over the shorter of the lease term or useful life of the underlying asset. Interest accretion on the finance lease liabilities is recorded as interest expense. For both operating and finance leases, lease expense related to variable payments is recognized as incurred based on performance or usage in accordance with the contractual agreements. For short-term lease arrangements with a term of one year or less, the Company has elected to recognize the related lease payments on a straight-line basis over the lease term without recording related ROU assets and lease liabilities.

The Company evaluates changes to the terms and conditions of a lease contract to determine if they result in a new lease or a modification of an existing lease. For lease modifications, the Company remeasures and reallocates the remaining consideration in the contract and reassesses the lease classification at the effective date of the modification.

The Company uses significant assumptions and judgment in evaluating its lease contracts and other agreements, including the determination of whether an agreement is or contains a lease, whether a change in the terms and conditions of a lease contract represent a new or modified lease, whether a lease represents an operating or finance lease, the discount rate used to determine the present value of lease obligations, and the term of a lease embedded in its manufacturing supply agreements.

Research and Development Expenses

Research and development costs are expensed as they are incurred. Research and development expenses consist primarily of salaries and benefits of research and development personnel, costs related to research activities, preclinical studies, clinical manufacturing, technical development, and overhead and facility-related costs.

The Company makes payments in connection with clinical trials under contracts with contract research organizations that support conducting and managing clinical trials. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Generally, these agreements set forth the scope of work to be performed at a fixed fee, unit price, or on a time and materials basis. A portion of the obligation to make payments under these contracts depends on factors such as the successful enrollment or treatment of patients or the completion of other clinical trial milestones.

Expenses related to clinical trials are accrued based on estimates and/or representations from service providers regarding work performed, including actual level of patient enrollment, completion of patient trials, and progress of the clinical trials. Other incidental costs related to patient enrollment or treatment are accrued when reasonably certain. Similarly, the Company accrues expenses related to the work performed by contract manufacturing organizations based on the progress of the work performed. If the amounts the Company is obligated to pay under clinical trial agreements and manufacturing agreements are modified (for instance, as a result of changes in the clinical trial protocol or scope of work to be performed), the accruals are adjusted accordingly. Revisions to contractual payment obligations are charged to expense in the period in which the facts that give rise to the revision become reasonably certain.

The Company may be obligated to make upfront payments upon execution of certain research and development agreements. Advance payments, including nonrefundable amounts, for goods or services that will be used or rendered for future research and development activities are deferred and included in prepaid expenses and other current assets or other non-current assets in the consolidated balance sheets. Such amounts are recognized as expense as the related goods are delivered or the related services are performed, or at such time when the Company does not expect the goods to be delivered or services to be performed.

Share-Based Compensation

The Company accounts for its share-based compensation in accordance with ASC 718, Compensation—Stock Compensation (ASC 718). ASC 718 requires all share-based payments to employees and directors, including grants of incentive stock options, nonqualified stock options, restricted stock awards, unrestricted stock awards, or restricted stock units, to be recognized as expense based on their grant date fair values. The determination of grant date fair value may require the Company to make assumptions as further discussed below. Changes in the assumptions can materially affect the fair value and ultimately how much share-based compensation expense is recognized. These assumptions are subjective and generally require significant analysis and judgment to develop.

Stock Options

The Company's determination of the fair value of stock options with time-based vesting on the date of grant utilizes the Black-Scholes option-pricing model and is impacted by the Company's common stock price as well as other variables including, but not limited to, the expected term that options will remain outstanding, expected common stock price volatility over the expected term of the option awards, risk-free interest rates and expected dividends.

The fair value of a stock-based award is recognized over the period during which an optionee is required to provide services in exchange for the option award, known as the requisite service period (usually the vesting period) on a straight-line basis. Stock-based compensation expense is recognized based on the fair value determined on the date of grant and is reduced for forfeitures as they occur.

Restricted Stock Awards, Unrestricted Stock Awards, and Restricted Stock Units

The fair value of restricted stock awards, unrestricted stock awards, and restricted stock units (collectively, awards) without a market condition (e.g., certain market capitalization thresholds) is the fair value of our common stock on the grant date. Vesting of awards is accelerated for certain employees in the event of a change in control or in the event that we remove the employee with or without cause from their position.

The Company estimates the fair value of awards subject to market conditions on the grant date using a *Monte Carlo* simulation model. For awards with vesting subject to the fulfillment of both market and performance condition, share-based compensation expense is recognized using the accelerated attribution method beginning when the achievement of the performance condition becomes probable over the applicable service period. The amount of share-based compensation expense is dependent on our periodic assessment of the probability of the performance condition being satisfied and our estimate, which may vary over time, of the number of shares that will ultimately be issued. If the performance condition is not met, no compensation expense is recognized, and any previously recognized compensation cost is reversed.

3. Fair Value of Financial Instruments

The fair value of the Company's financial assets by level within the fair value hierarchy were as follows (in thousands):

	September 30, 2023		
	Level 1	Level 2	Level 3
Money market fund (cash equivalent)	$ 105,403	$ —	$ —
Money market fund (long-term restricted cash)	4,929	—	—
Marketable securities:			
Commercial paper	—	80,156	—
Corporate debt	—	5,454	—
Government agency	—	290,826	—
Total assets measured at fair value	$ 110,332	$ 376,436	$ —

	December 31, 2022		
	Level 1	Level 2	Level 3
Money market fund (cash equivalent)	$ 57,697	$ —	$ —
Money market fund (long-term restricted cash)	2,501	—	—
Marketable securities:			
Commercial paper	—	129,810	—
Corporate debt	—	11,866	—
Government agency	—	48,980	—
Total assets measured at fair value	$ 60,198	$ 190,656	$ —

The fair value of financial assets categorized within Level 1 of the fair value hierarchy is determined by using unadjusted quoted prices that are available in active markets for identical assets and liabilities. The fair value of financial assets categorized within Level 2 of the fair value hierarchy is determined by using inputs other than Level 1 quoted prices that are directly or indirectly observable. Inputs can include quoted prices for similar assets and liabilities in active markets or quoted prices for identical assets and liabilities in inactive markets. Related inputs can also include those used in valuation or other pricing models, such as interest rates and yield curves that can be corroborated by observable market data.

The Company did not transfer any assets measured at fair value on a recurring basis between levels during the nine months ended September 30, 2023 or the year ended December 31, 2022.

4. Marketable Securities

Available-for-sale marketable securities were as follows (in thousands):

	September 30, 2023			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Commercial paper	$ 80,176	$ —	$ (20)	$ 80,156
Corporate debt	5,460	—	(6)	5,454
Government agency	290,866	16	(56)	290,826
Total	$ 376,502	$ 16	$ (82)	$ 376,436

	December 31, 2022			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Commercial paper	$ 129,810	$ —	$ —	$ 129,810
Corporate debt	11,923	—	(57)	11,866
U.S. government agency	49,144	9	(173)	48,980
Total	$ 190,877	$ 9	$ (230)	$ 190,656

All of the Company's available-for-sale debt marketable securities held as of September 30, 2023 had contractual maturities of less than one year. The Company had 26 securities in an unrealized loss position with an aggregate related fair value of $169.9 million as of September 30, 2023. All securities in an unrealized loss position as of September 30, 2023 had been in a loss position for less than 12 months. Unrealized losses on available-for-sale marketable securities as of September 30, 2023 were not significant and were

primarily due to changes in interest rates, including market credit spreads, and not due to increased credit risks associated with specific securities. Accordingly, no allowance for credit losses related to the Company's available-for-sale marketable securities was recorded for the three or nine months ended September 30, 2023. The Company does not intend to sell these securities or expect to be required to sell the investments before recovery of their amortized cost bases, which may be at maturity.

5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following (in thousands):

	September 30, 2023	December 31, 2022
Prepaid research and development costs	$ 10,660	$ 8,361
Other prepaid expense	2,477	1,192
Accrued interest	1,675	511
Other receivables	5,448	1,964
Total prepaid expenses and other current assets	$ 20,260	$ 12,028

6. Collaboration Agreement

In December 2022, the Company entered into the Kite Collaboration Agreement, a Common Stock Purchase Agreement with Gilead (Gilead SPA) and a Standstill Agreement with Gilead (Standstill Agreement). Upon closing in January 2023, Kite made an upfront payment of $225.0 million and obtained a license to co-develop and co-commercialize CART-ddBCMA, and next-generation autologous and non-autologous CAR-T cell therapy products that use the same D-domain BCMA binder used in CART-ddBCMA, in each case for the treatment of multiple myeloma. The Company also granted Kite the ability to negotiate a development and commercialization license for the inclusion of a limited number of pre-specified additional autologous CAR-T-cell therapy products for the treatment of multiple myeloma, which can only be exercised by Kite after the Company provides to Kite a phase 1 clinical study report.

In addition to the upfront consideration, the Company will be eligible to receive clinical, regulatory, and commercial milestone payments of up to $335.0 million, $635.0 million and $507.5 million, for CART-ddBCMA, each next-generation autologous CAR-T cell therapy product, and each non-autologous CAR-T cell therapy product, respectively. In the United States, the Company and Kite will equally share profits and losses from the commercialization of CART-ddBCMA and any next-generation autologous CAR-T cell therapy product for which the Company has exercised its option to co-promote with Kite (collectively, the Co-Promote Products). The Company has the option to designate next-generation autologous CAR-T therapy product as a Co-Promote Product after Kite provides the first phase 1 clinical study report for such product with the proposed core development plan and budget. For Co-Promote Products outside of the United States and for any other products worldwide that are not a Co-Promote Product (Non-Co-Promote Products), including any next-generation autologous CAR-T cell therapy product for which the company has opted out of designating as a Co-Promote Product, the Company will be eligible for tiered royalties in the low to mid teen percentages. The Company and Kite will jointly develop the Co-Promote Products in accordance with mutually agreed development plans and development budgets. On a Co-Promote Product-by-Co-Promote Product basis, the Company may, upon advance written notice to Kite, opt out of sharing development costs and profits and losses from the commercialization of such Co-Promote Product (for example, CART-ddBCMA), in which case, it will become a Non-Co-Promote Product and eligible for tiered royalties in the low to mid teen percentages.

Other than certain items expressly set forth in the Kite Collaboration Agreement, the out-of-pocket development costs for activities conducted in the United States for Co-Promote Products will be shared equally by the Company and Kite. In the United States, the Company and Kite will be jointly responsible for commercialization of the Co-Promote Products. The out-of-pocket development costs for activities conducted outside the United States as part of a global clinical trial for Co-Promote Products will be borne 60% (for ex-U.S. patients) by Kite and 40% (for U.S. patients) by the Company, however Kite will be solely responsible for the costs for country-specific clinical trials outside the United States and chemistry, manufacturing and control (CMC) commercial readiness. Kite will be solely responsible for the conduct of development and commercialization of the Non-Co-Promote Products at its sole cost. Kite will manufacture the licensed products and bear the CMC commercial readiness costs and capital expenses, except that the Company is responsible for manufacturing CART-ddBCMA prior to transferring the manufacturing process to Kite during which the cost of manufacturing clinical trial material will be shared.

Unless earlier terminated, the Kite Collaboration Agreement will continue in effect until no licensed products are being developed or commercialized. The Kite Collaboration Agreement is subject to termination provisions including termination by a party for the other party's uncured, material breach. In the event of certain terminations of the Kite Collaboration Agreement, the Company is entitled to certain reversionary rights, including access to and continuity of manufacturing, with respect to the terminated products.

Stock Purchase Agreement and Standstill Agreement

In connection with the Kite Collaboration Agreement and upon its closing in January 2023, Gilead made an equity investment of $100.0 million by purchasing 3,478,261 shares of Arcellx common stock at a fixed per share price of $28.75 pursuant to the Gilead SPA, which represented a $15.3 million discount on the sale of the Company's common stock based on the share price on the date of closing.

Revenue Recognition

The Company evaluated the agreement with Kite and determined that the obligation to co-develop the ddBCMA license and the Company's research and development obligations to develop CART-ddBCMA were within the scope of ASC 606 because these activities are ordinary Company activities and Kite meets the definition of a customer with respect to this combined performance obligation. The revenue to be recognized will be recorded on a cost-to-cost percentage of completion basis over the period of time the Company is performing the research and development activities.

Transaction Price

In determining the transaction price, the Company adjusts consideration for the effects of the time value of money if there is a significant benefit of financing. The Company assessed our collaboration agreements and concluded that no significant financing components were present. The Company's assessment of the transaction price upon the signing of the Kite Collaboration Agreement included an analysis of the amounts it expects to receive, which as of September 30, 2023 totaled $176.9 million. The transaction price consists of fixed consideration of $220.9 million offset by a variable consideration of $44.1 million. Variable consideration results from net amounts expected to be paid to Kite over the course of the contract and are subject to change. Fixed consideration includes a reduction of a $15.3 million deemed discount on the shares sold to Gilead as they were sold at a price less than the closing price of the Company's stock on the expiration date of the antitrust waiting period. There were no material direct transaction costs related to the transaction.

Promises and Performance Obligation

The Company's promises under the Kite Collaboration Agreement include development, manufacture, and commercialization licenses, research and development activities, manufacturing activities, and the transfer of manufacturing know-how to Kite (collectively, the research and development services). These promises represent a single combined performance obligation as the promises are not distinct from each other. The Company determined that the license and research and development services are combined based on the specialized nature of the Company's know-how and manufacturing process.

The Company recognizes revenue over time using a cost-to-cost input measure of progress. In applying the cost-to-cost input measure of progress, the Company used actual costs incurred relative to total budgeted costs expected to be incurred for the combined performance obligation.

Cost-sharing Reimbursements

The CART-ddBCMA therapy product is intended to be developed through at least three research and development and clinical trial programs, iMMagine-1, iMMagine-2, and iMMagine-3, where the Company's research and development obligations under the Kite Collaboration Agreement, other than certain items expressly set forth in the Kite Collaboration Agreement, includes a co-share of 50/50 (with respect to the iMMagine-1 and iMMagine-2 trials) and 40/60 (with respect to certain aspects of the iMMagine-3 trial) of the joint development costs associated with CART-ddBCMA and any other Co-Promote Products. Kite will be conducting and paying for all activities relating to the iMMagine-2 and 3 trials and the Company will reimburse Kite from 40% to 50% of these costs. Reimbursement costs expected to be received from Kite or paid to Kite represent variable consideration and is included in the estimated transaction price. The Company uses the expected value method to estimate variable consideration and updates estimates at each reporting date.

Q3 Activity

As of September 30, 2023, receivable from collaboration partner totaled $31.5 million, which consists of reimbursable costs. Revenue recognized is presented as collaboration revenue in the condensed consolidated financial statements. As of September 30, 2023 the balances in contract liability were as follows (in thousands):

Contract liability	September 30, 2023
Fixed transaction price	220,925
Reimbursable costs for the nine months ended September 30, 2023	41,516
Less: revenue recognized as of September 30, 2023	(47,171)
Total contract liability	215,270
Less: current portion	(94,180)
Noncurrent portion	121,090

7. Commitments and Contingencies

Leases

The Company is obligated for operating lease payments for its facilities in Rockville and Gaithersburg, Maryland and Redwood City, California. See Note 9 Leases.

Manufacturing Services Agreement with Lonza Houston, Inc.

Pursuant to the manufacturing services agreement with Lonza Houston, Inc. (Lonza) in connection with the development and manufacture of autologous drug product CART-ddBCMA (Lonza Agreement), the Company entered into a statement of work with Lonza (Lonza SOW) in February 2022, for the technology transfer and cGMP manufacturing of CART-ddBCMA and potentially other pipeline products. The Lonza SOW contains an embedded lease as the Company has exclusive use of, and control over manufacturing facilities during the contractual term. The Lonza SOW also contains an agreement to purchase inventory that is accounted for separately. In September 2023, the Company signed Amendment 1 to the Lonza SOW. Amendment 1 increased the quantity of manufacturing slots from September 2023 through the end of the lease and increased the amount of capacity and equipment exclusively controlled by Arcellx. The term of the Lonza SOW expires December 31, 2024, unless earlier terminated by either party or unless extended due to certain delays or suspensions or by mutual agreement. The Lonza SOW was non-cancellable for the first six months of the term and carried minimum non-cancellable costs including upfront payments, milestone fees, and fixed monthly payments during the related period. Subsequent to the non-cancellable period, the Company may terminate the arrangement for any reason upon 12 months prior notification to Lonza.

As of September 30, 2023, the Company's minimum non-cancellable costs payable to Lonza was approximately $58.4 million, of which $48.3 million is reflected in the current finance lease liabilities, $1.3 million in accrued liabilities, and $14.1 million in accounts payable. Variable costs under this arrangement include materials, external testing, and other services. The Company paid $10.6 million and $31.1 million under this arrangement during the three and nine months ended September 30, 2023, respectively. The Company paid $2.8 million and $13.7 million under this arrangement during the three and nine months ended September 30, 2022, respectively.

Commercial and Development Milestones

In addition to the arrangement with Lonza, we have entered into other contracts in the normal course of business with CROs, CMOs, and other third parties for preclinical research studies and testing, clinical trials, and manufacturing services. These contracts do not contain any minimum purchase commitments and are cancelable by us upon prior notice. For such contracts, payments due upon cancellation consist only of payments for services provided and expenses incurred, including non-cancelable obligations of our service providers, up to the date of cancellation. We have also entered into agreements with certain vendors for the provision of goods and services, which include manufacturing services with CMOs and development services with CROs. These agreements may include certain provisions for purchase obligations and termination obligations that could require payments for the cancellation of committed purchase obligations or for early termination of the agreements. The amount of the cancellation or termination payments vary and are based on the timing of the cancellation or termination and the specific terms of the agreement. In addition, certain agreements with our CMOs and third-party vendors contain (a) development and commercial milestone payments and low single-digit royalties on worldwide net sales for certain products we sell that incorporate certain goods provided by our manufacturers and suppliers, (b) development milestones of up to $28.8 million in the aggregate and (c) commercial milestones of up to $52.0 million in the aggregate, along with royalty buyout provisions.

Purchase Commitments

The Company conducts product research and development programs through a combination of internal and collaborative programs that include, among others, arrangements with universities, contract research organizations and clinical research sites. The Company has contractual arrangements with these organizations; however, these contracts are generally cancelable on 30 days' notice and the obligations under these contracts are largely based on services performed.

Contingencies

From time to time, the Company may be subject to various litigation and related matters arising in the ordinary course of business. The Company records a provision for a liability when it believes that it is both probable that a liability has been incurred and the amount can be reasonably estimated. Significant judgment is required to determine both probability and the estimated amount. As of September 30, 2023 and December 31, 2022, the Company was not involved in any material legal proceedings.

Indemnification Agreements

As permitted under Delaware law, the Company indemnifies its executive officers and directors for certain events or occurrences while the executive officer or director is, or was, serving at our request in such capacity. The term of this indemnification is for the officer's or director's lifetime. Additionally, the Company has entered into and expects to continue to enter into indemnification agreements with its executive officers and directors. Further, in the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners, and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date however, the Company has not incurred any material costs as a result of such indemnifications nor experienced any losses related to them. As of September 30, 2023, the Company was not aware of any claims under indemnification arrangements and does not expect significant claims related to these indemnification obligations. Therefore, no related reserves were established.

8. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	September 30, 2023	December 31, 2022
Research and development accrued expenses	$ 3,462	$ 3,201
Accrued bonus	3,238	5,347
Other liabilities	10,216	3,131
Total accrued liabilities	$ 16,916	$ 11,679

9. Leases

Operating Leases

In July 2022, the Company entered into a new operating lease agreement for 57,902 square feet of office and laboratory space in Rockville, Maryland for a term of approximately 12.9 years at inception with remaining undiscounted minimum lease payments of approximately $33.1 million as of September 30, 2023. The original Rockville lease contained annual rent escalation and rent abatement clauses as well as an allowance of approximately $12.1 million for tenant improvements. During the nine months ended September 30, 2023, the landlord and the Company agreed to convert $2.8 million of rent abatement to additional tenant improvement allowance. The change was accounted for as a lease modification and the Company recorded an increase in the right-of-use asset and lease liability of $1.3 million. The Company consulted a qualified third-party valuation specialist and determined an incremental borrowing rate of 10.2% to be used as the discount rate for re-measuring the related operating lease liabilities on the modification date. The Rockville lease provides for optional two five-year extensions. The optional period is not included in the lease term used to determine the ROU asset or lease liability associated with this lease as the Company did not consider it reasonably certain it would exercise the option.

In May 2022, the Company entered into a new operating lease agreement for 51,822 square feet of office and laboratory space in Redwood City, California for a term of approximately 11.7 years at inception with remaining undiscounted minimum lease payments of approximately $54.3 million as of September 30, 2023. The Redwood City lease contains annual rent escalation and rent abatement clauses as well as an allowance of approximately $9.8 million for tenant improvements. The Redwood City lease provides for an optional five-year extension. The optional period is not included in the lease term used to determine the ROU asset or lease liability associated with this lease as the Company did not consider it reasonably certain it would exercise the option. The Company consulted a qualified third-party valuation specialist and determined an incremental borrowing rate of 8.5% to be used as the discount rate for measuring the related operating lease liabilities.

The Company also leases office and laboratory space in Gaithersburg, Maryland that has a term that expires in 2030 unless renewed. This operating lease agreement contains rent escalation, rent abatement clauses, tenant improvement allowances, and optional renewal clauses.

All three operating leases include variable lease payments, which are primarily related to common area maintenance, taxes, and utility charges. The Company also has short-term operating leases with a term of one year or less.

Finance Leases

The Lonza SOW entered into in February 2022 with Lonza contains an embedded lease as the Company has the exclusive use of, and control over, a portion of the manufacturing facility and equipment of the supplier during the contractual term of the manufacturing arrangement. Lease commencement occurred during the three months ended September 30, 2022 when the applicable manufacturing facility and equipment became available for cGMP manufacturing under the Company's exclusive use and control. The arrangement provides the Company the ability to early terminate for any reason upon 12 months prior notification to Lonza. The Company did not consider it reasonably certain it would terminate the arrangement when determining the lease term. The arrangement expires in December 2024.

In September 2023, the Company signed Amendment 1 to the Lonza SOW entered into in February 2022. Amendment 1 increased quantity of manufacturing slots from September 2023 through the end of the lease in December 2024, providing additional right of use to the Company that was previously considered "shared" capacity under the Lonza SOW. The Company now has exclusive use of, and control over, the additional facility space and equipment through the remainder of the lease term.

This change under Amendment 1 was accounted for as a lease modification, and the Company remeasured the lease liabilities for the modified lease as of the Amendment effective date. The remeasurement of the lease liabilities included fixed consideration with an undiscounted value of approximately $51.7 million, or $48.5 million discounted using the expected payment timeline and the incremental borrowing rate of 10.8%, resulting in an increase of $15.9 million in lease liabilities. As the Company acquired ROU assets that represented assets acquired for research and development activities that did not have an alternative future use, the Company recorded the ROU assets as R&D expense immediately.

The Company elected the practical expedient to combine the lease component and the non-lease components associated with the lease component as a single lease component, except as related to the non-lease component associated with purchase of inventory. The related ROU assets represent assets acquired for research and development activities with no alternative future use and therefore were immediately expensed.

The Company's total lease costs were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Finance lease costs:				
Right-of-use assets with no alternative future use	$ 16,985	$ 63,147	$ 18,247	$ 63,147
Amortization of right-of-use assets	25	25	75	77
Interest on lease liabilities	960	598	2,871	604
Operating lease costs	1,529	1,472	4,597	2,299
Short-term lease costs	8	7	24	750
Variable lease costs	2,293	675	5,435	953
Total lease costs	$ 21,800	$ 65,924	$ 31,249	$ 67,830

Future minimum lease payments were as follows (in thousands) as of September 30, 2023:

	Operating Leases	Finance Leases
Remainder of 2023	$ 1,523	$ 20,226
2024	7,554	35,783
2025	8,161	—
2026	8,412	—
2027	8,672	—
2028	8,939	—
Thereafter	49,934	—
Total lease payments	93,195	56,009
Less:		
Tenant improvement incentive	(4,719)	—
Imputed interest	(33,798)	(1,968)
Present value of total lease liabilities	$ 54,678	$ 54,041

Supplemental cash flow information related to leases is as follows (in thousands):

	Nine Months Ended September 30, 2023	2022
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from finance leases	$ 3,810	$ —
Operating cash flows from operating leases	2,826	1,191
Financing cash flows from finance leases	14,010	9,295
Right-of-use assets obtained in exchange for new finance lease liabilities	18,046	—
Right-of-use assets obtained in exchange for new operating lease liabilities	1,296	29,562

Weighted-average remaining lease terms and discount rates were as follows as of September 30, 2023:

Weighted-average remaining lease term — finance leases	1.3 years
Weighted-average remaining lease term — operating leases	10.6 years
Weighted-average discount rate — finance leases	10.8%
Weighted-average discount rate — operating leases	9.1%

10. Redeemable Convertible Preferred Stock and Stockholders' Equity

"At-the-Market" Offering Program

In May 2023, the Company entered into a sales agreement (Sales Agreement) with Stifel, Nicolaus & Company (Stifel) with respect to an at-the-market (ATM) offering program under which the Company may issue and sell, from time to time and at management's sole discretion, shares of the Company's common stock, in an aggregate offering amount of up to $350.0 million. No sales of the Company stock have been made under this arrangement as of September 30, 2023.

Gilead SPA

On January 26, 2023, the Company issued and sold an aggregate of 3,478,261 shares of common stock in a private placement to Gilead at a price of $28.75 per share for an aggregate purchase price of $100.0 million. The shares were sold pursuant to the Gilead SPA in connection with the Kite Collaboration Agreement and the transaction is considered part of the arrangement. The shares were sold at a discount of $4.39 per share as compared to the closing price of the stock on the date of the expiration of anti-trust provisions and accordingly, the $15.3 million discount is reflected as an increase to additional paid-in capital and decrease to the total fixed transaction price in the arrangement. See Note 6 - Collaboration Agreement.

Common Stock

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, as may be declared by the board of directors, if any. As of the date of the filing of this Quarterly Report on Form 10-Q, no dividends have been declared or paid by the Company.

In the event of any liquidation or dissolution of the Company, the holders of common stock are entitled to the assets of the Company legally available for distribution.

Redeemable Convertible Preferred Stock

In connection with the Company's IPO in February 2022, all outstanding shares of the Company's redeemable convertible preferred stock automatically converted into shares of common stock at the applicable conversion ratio then in effect. The Company's outstanding shares of preferred stock were converted into 24,785,564 shares of common stock.

11. Share-Based Compensation

The Company's 2017 Equity Incentive Plan (the 2017 Plan) provided for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, and restricted stock awards to the Company's employees, directors, and consultants. The 2017 Plan terminated one business day prior to effectiveness of the 2022 Equity Incentive Plan (the 2022 Plan) with respect to the grant of future awards. The 2022 Plan became effective on February 3, 2022 and provides for the grant of incentive stock options to the Company's employees and for the grant of non-statutory stock options, stock appreciation rights, restricted stock, restricted stock units (RSUs), and performance awards to the Company's employees, directors, and consultants.

As of September 30, 2023, the aggregate number of shares of common stock that were able to be issued pursuant to equity awards under the 2022 Plan was 6,502,174 shares, which included shares subject to awards granted under the 2017 Plan that expire or otherwise terminate without having been exercised in full or are forfeited to or repurchased by the Company (provided that the maximum number of shares that may be added to the 2022 Plan pursuant to awards under the 2017 Plan is 6,269,300). The number of shares of common stock reserved for issuance under the 2022 Plan is cumulatively increased on the first day of each fiscal year, which began with the Company's 2023 fiscal year and will end on the ten year anniversary of the date the Company's board of directors approved the 2022 Plan, by an amount equal to the least of (i) 6,502,174 shares, (ii) 5% of the total number of shares of common stock outstanding as of the last day of the immediately preceding fiscal year, or (iii) a lesser number of shares determined by the administrator of the 2022 Plan.

Share-based compensation expense by type of award was as follows (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Stock options	$ 5,372	$ 3,569	$ 15,279	$ 10,997
Restricted stock units	3,149	1,162	9,090	$ 2,807
Restricted stock units - chief executive officer	1,963	598	6,374	1,950
ESPP	130	—	431	—
Total share-based compensation expense	$ 10,614	$ 5,329	$ 31,174	$ 15,754

Share-based compensation expense as reflected in the condensed consolidated statement of operations and comprehensive loss was as follows (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Research and development	$ 2,831	$ 1,551	$ 8,234	$ 5,274
General and administrative	7,783	3,778	22,940	10,480
Total share-based compensation expense	$ 10,614	$ 5,329	$ 31,174	$ 15,754

Stock Options

Stock options granted under the 2017 Plan and the 2022 Plan vest over one to four years and expire after 10 years. The Company uses the Black Scholes option pricing model to determine the grant date fair value of stock options.

A summary of stock option activity for awards under the 2017 Plan and the 2022 Plan is presented below:

	Options Outstanding and Exercisable			
	Shares Subject to Outstanding Options	Weighted Average Exercise Price per Option	Weighted Average Remaining Contractual Life Term (in Years)	Aggregate Intrinsic Value (1) (in thousands)
Outstanding as of January 1, 2023	8,053,704	$ 9.59	8.3	$ 172,294
Options Granted	890,358	31.56		
Options Forfeited	(18,816)	10.86		
Options Exercised	(776,837)	5.90		
Outstanding as of September 30, 2023	8,148,409	$ 12.34	8.0	$ 191,980
Exercisable as of September 30, 2023	4,112,539	$ 8.88	7.7	$ 111,054

(1) The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying options and the estimated fair value of the common stock for the options that were in the money as of September 30, 2023.

Restricted Stock Units (RSUs)

RSUs granted under the 2022 Plan generally vest annually over three or four years. The Company uses the market price of the Company's common shares on the date of grant to determine the fair value of RSUs.

A summary of RSU activity for awards under the 2022 Plan, excluding the 2023 RSU Award and 2021 RSU Award (each defined below) granted to the chief executive officer, is presented below:

	Shares Subject to Outstanding Awards	Weighted Average Grant Date Fair Value
Outstanding as of January 1, 2023	927,954	$ 17.20
RSUs Granted	809,491	31.56
RSUs Vested	(284,047)	16.72
RSUs Forfeited	(37,603)	22.77
Outstanding as of September 30, 2023	1,415,795	$ 25.36

Restricted Stock Units - Chief Executive Officer

2023 RSU Award

In January 2023, the Company granted 495,000 RSUs (the 2023 RSU Award) to its chief executive officer. The 2023 RSU Award has two different scenarios to vesting. The first vesting scenario is subject to service and market conditions. The second vesting scenario adds a performance condition. Each RSU granted in the 2023 RSU Award entitles the chief executive officer to one share of common stock upon vesting subject to the service, performance, and market conditions. All 495,000 RSUs were outstanding and no RSUs were vested as of September 30, 2023.

Service Condition

The service condition to vesting of the 2023 RSU Award requires the chief executive officer's continued employment with the Company through the achievement of any of the performance and market conditions.

Performance Condition

The performance condition to vesting of the 2023 RSU Award requires the consummation of a change in control event.

Market Condition

The market condition to vesting of the 2023 RSU Award involves evaluating Company market value thresholds depending upon which of the two vesting scenarios is applicable at the time of measurement.

The Company value is measured each June 30 and December 31 subsequent to the grant of the 2023 RSU Award and represents the Company's Enterprise Value. The Company's Enterprise Value is determined using the total market capitalization of the Company based on the average closing trading price of one share of the Company's common stock over the 60-day period ending on the day prior to the applicable semi-annual measurement date, less cash. On the semi-annual measurement date, (i) one-sixth of the award will vest if a minimum Enterprise Value of $2.5 billion is achieved, (ii) all of the award will vest if a $5.0 billion Enterprise Value is achieved, and (iii) a portion of the award will vest based on a straight-line interpolation if an Enterprise Value of between $2.5 billion and $5.0 billion is achieved.

The Company value on a change in control event is measured on the date of the change in control and represents the aggregate amount of deal consideration paid at the closing of the change in control by an acquirer for the Company's shares of common stock in connection with such change in control. Upon a change in control, (i) one-sixth of the award will vest if a minimum deal consideration of $2.5 billion is achieved, (ii) all of the award will vest if a $5.0 billion deal consideration is achieved, and (iii) a portion of the award will vest based on a straight-line interpolation if a deal consideration of between $2.5 billion and $5.0 billion is achieved.

The Company utilized Monte Carlo simulation models to estimate the fair value of the 2023 RSU Award on the date of grant in each of the two vesting scenarios. The application of the Monte Carlo simulation model to each of the two vesting scenarios requires various subjective assumptions, including the following:

- Expected Time to Award End Date – The expected time to the award end date is based on the Company's best estimate of the period of employment for the chief executive officer or the achievement of the performance condition, i.e., the change in control event.
- Expected Equity Volatility – Due to the limited company-specific historical and implied volatility data, the Company based its computation of expected volatility on the historical volatility of a representative group of public companies with similar characteristics to the Company (e.g., public entities of similar size, complexity, stage of development, and industry focus) in addition to the historical volatility of the Company. The historical volatility for the representative group of public companies was calculated based on a period commensurate with the expected time to the award end date.
- Risk-Free Interest Rate – The risk-free interest rate is based on a U.S. Treasury instrument which term is consistent with the expected time to the measurement dates.

The Company determined the fair value of the 2023 RSU Award using third-party valuation reports. The Company considered several objective and subjective factors, including weighted probability of various scenarios, operating and financial performance, and general and industry-specific economic outlook, among other factors. The assumptions used in the Monte Carlos simulation models to determine the grant date fair value of the 2023 RSU Award for the two vesting scenarios were as follows:

	Semi-Annual Measurement	Change in Control
Time to award end date	10 years	5 years
Equity volatility	75.0%	75.0%
Risk-free interest rate	3.8%	3.9%
Fair value of the 2023 RSU award (in thousands)	$ 13,811	$ 10,999

The Company began recognizing share-based compensation expense using a fair value of $13.8 million on an accelerated attribution basis over a 10-year anticipated service period according to the semi-annual measurement scenario. The performance condition under the change in control scenario was not deemed probable as of September 30, 2023. The Company recognized $1.4 million and $4.7 million in share-based compensation expense related to the 2023 RSU Award during the three and nine months ended September 30, 2023, respectively.

2021 RSU Award

In June 2021, the Company granted 952,804 RSUs (the 2021 RSU Award) to its chief executive officer. The 2021 RSU Award is subject to service, performance, and market conditions. In December 2021, the Company added alternative performance conditions for vesting of the same RSUs. These additional performance conditions provided alternative paths to vesting from the 2021 RSU Award; its vesting conditions remained the same, i.e., the original award was not modified.

Each RSU granted in the 2021 RSU Award entitles the chief executive officer to one share of common stock upon vesting subject to the service, performance, and market conditions. All 952,804 RSUs were outstanding and no RSUs were vested as of September 30, 2023 and December 31, 2022.

Service Condition

The service condition to vesting of the 2021 RSU Award requires the chief executive officer's continued employment with the Company through the achievement of any of the performance and the market conditions.

Performance Condition

The performance conditions to vesting of the 2021 RSU Award include (i) the consummation of a change in control event, (ii) the consummation of the first firm commitment underwritten public offering covering the offer and sale of Company shares, the consummation of the direct listing or direct placement of Company shares on a publicly traded exchange, or the completion of a merger or consolidation with a special purpose acquisition company in which the shares of the surviving or parent entity are listed on a national securities exchange (IPO), or (iii) a change in control following an IPO. The Company satisfied the IPO performance condition in February 2022 upon completion of the IPO.

Market Condition

The market condition to vesting of the 2021 RSU Award involves Company value thresholds depending upon which of the vesting scenarios is applicable at the time of measurement.

The Company value is measured each June 30 and December 31 following the IPO (subject to applicable lock-up period) and represents the Company's Enterprise Value. The methodology to determine the Company's Enterprise Value and the vesting thresholds on the semi-annual measurement dates are the same as those under the 2023 RSU Award.

The Company value on a change in control is measured on the date of the change in control. The methodology to determine the Company value and the vesting thresholds on the change in control date are the same as those under the 2023 Award.

The Company utilized Monte Carlo simulation models to estimate the fair value of the 2021 RSU Award on the date of grant in each of the three vesting scenarios.

Upon completion of the IPO in February 2022, the IPO performance condition of the 2021 RSU Award was satisfied and the Company began recognizing share-based compensation expense on an accelerated attribution basis over the 10-year anticipated service period based on a $10.3 million aggregate fair value according to the IPO scenario. No other performance condition was deemed probable as of September 30, 2023. The Company recognized $0.5 million and $1.7 million in share-based compensation expense related to this award during the three and nine months ended September 30, 2023, respectively.

12. Income Taxes

The Company has recorded an income tax expense of zero and $41 thousand for the three and nine months ended September 2023 respectively, and zero for the same periods in 2022.

Based on the available objective evidence during the three and nine months ended September 30, 2023, the Company believes it is more likely than not that the tax benefits of U.S. losses incurred during prior years may not be realized. Accordingly, the Company did not record the tax benefits of U.S. losses previously incurred as of September 30, 2023. The primary difference between the effective tax rate and the statutory tax rate relates to the valuation allowance on the Company's U.S. losses.

13. Net Loss Per Share Attributable to Common Stockholders

The Company's potentially dilutive securities include options to purchase common stock, unvested shares of restricted common stock redeemable convertible preferred stock, restricted stock units, and restricted stock units - executive officer. The Company's potentially dilutive securities have been excluded from the computation of diluted net loss per share as the effect would be anti-dilutive. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at period end, from the computation of diluted net loss per share attributable to common stockholders for the period indicated because including them would have had an anti-dilutive effect:

	September 30,	
	2023	**2022**
Options to purchase common stock	8,148,409	8,440,383
Unvested shares of restricted common stock from early exercises	—	—
Restricted stock units	1,415,795	881,624
Restricted stock units - executive officer	1,447,804	952,804
Employee Stock Ownership Plan (ESPP)	13,893	—
Total	11,025,901	10,274,811

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

You should read the following discussion and analysis of our financial condition and results of operations together with our condensed consolidated financial statements and the related notes thereto included elsewhere in this Quarterly Report on Form 10-Q for the three and nine months ended September 30, 2023 as well as in conjunction with 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, 2022. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business, include forward-looking statements that involve risks and uncertainties. You should review the section titled Special Note Regarding Forward-Looking Statements and Part II, Item 1A (Risk Factors) for a discussion of important factors that could cause our actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. For convenience of presentation, some of the numbers have been rounded in the text below. Our historical results are not necessarily indicative of the results that may be expected for any period in the future.

Overview

We are a clinical-stage biotechnology company reimagining cell therapy through the development of innovative immunotherapies for patients with cancer and other incurable diseases. We believe cell therapies are one of the forward pillars of medicine, and our mission is to advance humanity by engineering cell therapies that are safer, more effective and more broadly accessible. Although cell therapies have shown benefits to date, cell therapies have primarily been constrained to existing biologic structures, which has limited their impact and opportunity. Our novel synthetic binding scaffold, the D-Domain, is designed to overcome the limitations of traditional Chimeric Antigen Receptor T-cells (CAR-Ts). Existing cell therapy solutions, most of which use a biologic-based, single chain variable fragment (scFv) binding domain, tend to be difficult to manufacture, beneficial to a limited segment of patients, often result in high toxicity, and have narrow applicability in treatable indications. We believe we can address these limitations by engineering a new class of D-Domain powered cell therapies, including classical single infusion CAR-Ts called "ddCARs" and dosable and controllable universal CAR-Ts called "ARC-SparX", to address hematologic cancers, solid tumors, and indications outside of oncology, such as autoimmune diseases.

Our lead program is a BCMA-targeting ddCAR product candidate called "CART-ddBCMA", which is currently being evaluated in our pivotal Phase 2 "iMMagine-1" trial in patients with relapsed or refractory multiple myeloma (rrMM). We have partnered CART-ddBCMA with Kite Pharma Inc., a Gilead company (Kite), through our co-development/co-commercialization collaboration agreement (as described in more detail in the section below titled "Components of Results of Operations - Revenue" included in this Quarterly Report on Form 10-Q). We also are developing two clinical-stage ARC-SparX programs in Phase 1 trials, ACLX-001, which targets BCMA in rrMM, and our wholly-owned ACLX-002, which targets CD123 in relapsed or refractory acute myeloid leukemia (AML) and high-risk myelodysplastic syndrome (MDS).

Since our formation, we have devoted substantially all our resources to discovering and developing our product candidates. We have incurred significant operating losses to date. Our net losses were $90.5 million and $149.7 million for the nine months ended September 30, 2023 and 2022, respectively. Our accumulated deficit totaled $409.3 million as of September 30, 2023. These losses have resulted primarily from costs incurred in connection with research and development activities and general and administrative costs associated with our operations. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future, and our net losses may fluctuate significantly from period to period, depending on the timing of and expenditures on our planned research and development activities. We expect our operating expenses and capital requirements will increase substantially in connection with our ongoing activities, as we:

- Advance the clinical program for CART-ddBCMA and subsequent clinical trials focused on earlier lines of therapy in collaboration with our partners at Kite;
- Grow our supply and contract manufacturing infrastructure to support the continued development of CART-ddBCMA and our other product candidates;
- Initiate or continue to advance clinical trials to evaluate our clinical-stage ARC-SparX product candidates, ACLX-001 and ACLX-002, and other preclinical pipeline programs;
- Expand our pipeline of product candidates, including through our own product discovery and development efforts or through acquisition or in-licensing;
- Continue to develop our proprietary platforms to extend their use;
- Attract, hire, and retain additional clinical, scientific, manufacturing, management and administrative personnel;

•Add operational, financial, and management information systems and personnel, including personnel to support our product development, as well as to support us as a public reporting company;

•Determine and execute our long-term manufacturing strategy for CART-ddBCMA in collaboration with our partners at Kite;

•Pursue regulatory approval of product candidates that successfully complete clinical trials;

•Establish a sales, marketing and distribution infrastructure to commercialize any product candidate for which we may obtain regulatory approval;

•Obtain, maintain, expand and protect our intellectual property portfolio; and

•Incur costs associated with being a public company, including legal, accounting and auditing, investor relations, and compliance.

As a result, we will continue to require substantial additional funding to develop our product candidates and our platforms and to support our continuing operations. Our ability to generate product revenue will depend on the successful development, regulatory approval, and eventual commercialization of one or more of our product candidates. Until such time that we can generate significant revenue from product sales, if ever, we expect to finance our operations through public or private equity offerings, debt financings, marketing and distribution arrangements, other collaborations, strategic alliances, and licensing arrangements. We may be unable to raise additional funds or to enter into such agreements or arrangements on favorable terms, if at all. Our failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, results of operations, or financial condition, and could force us to delay, reduce or eliminate our product development or future commercialization efforts. We may also be required to grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our development efforts. We cannot assure you that we will ever be profitable or generate positive cash flow from operating activities.

Based on our expected operating cash requirements and capital expenditures, we believe our current cash and cash equivalents and investments in marketable securities are adequate to fund operations into 2026.

Recent Financings

In May 2023, we entered into a sales agreement (Sales Agreement) with Stifel, Nicolaus & Company (Stifel) with respect to an at-the-market offering program under which we may issue and sell, from time to time and at our sole discretion, shares of our common stock, in an aggregate offering amount of up to $350.0 million. Stifel acts as our sales agent and will use commercially reasonable efforts to sell shares of common stock from time to time, based upon instruction from us. We will pay Stifel up to 3.0% of the gross proceeds from the sales of any common stock sold pursuant to the Sales Agreement and have agreed to provide Stifel with customary indemnification and contribution rights, plus reimbursement for specified expenses it incurred in connection with entering into the agreement. No sales of our common stock have been made under this arrangement as of September 30, 2023.

In January 2023, we issued and sold 3,478,261 shares of our common stock to Gilead Sciences, Inc. (Gilead) for an aggregate purchase price of $100.0 million pursuant to a Common Stock Purchase Agreement (Gilead SPA) executed in connection with the Kite Collaboration Agreement.

Recent Developments

On August 14, 2023, we announced the U.S. Food and Drug Administration (FDA) had lifted the partial clinical hold that had been placed on our Phase 2 “iMMagine-1” trial evaluating CART-ddBCMA in patients with rrMM. The initial notice of clinical hold, announced on June 19, 2023, followed a recent patient death, which involved one clinical trial site treating a patient who was not eligible for CART ddBCMA infusion and subsequently managing the patient in a manner conflicting with our trial protocol. We recently received the final autopsy report for that patient, which identified the cause of death as a hemorrhage due to bone marrow biopsy. The hold was lifted after we aligned with the FDA on modifications to the trial protocol related to the prevention and management of the risk of adverse events within the trial. As a key effort to enhance protocol adherence, we retrained clinical sites. Additionally, the FDA has allowed an expansion of treatment options for therapies that subjects in our trial are permitted to receive between apheresis and CAR-T infusion (also known as bridging therapies), which better aligns our protocol with current clinical practice.

Working with our partners at Kite, we resumed screening and enrollment in iMMagine-1. Importantly, during the partial clinical hold, we continued to dose patients as the FDA had authorized dosing of 17 patients who were enrolled in the trial but had not yet been dosed prior to the clinical hold. We expect to present preliminary data from the iMMagine-1 trial in the second half of 2024.

Additionally, alongside Kite, we plan to initiate enrollment of the iMMagine-2 trial following the completion of enrollment for the iMMagine-1 trial.

On November 2, 2023, we announced the publication of an abstract for an upcoming oral presentation at the American Society of Hematology (ASH) Annual Meeting and Exposition taking place December 9-12, 2023 in San Diego, CA. The abstract contained updated data from the ongoing Phase 1 trial of CART-ddBCMA in patients with relapsed or refractory multiple myeloma.

Components of Results of Operations

Revenue

We have not generated any revenue from product sales and do not expect to do so in the near future. Our revenue consists of recognition of revenue from our collaboration with Kite for our research and development performed under the arrangement, recognized on a cost-to cost percentage of completion basis applied to the total estimated transaction price. In the future, we may generate revenue from payments received under this arrangement, and may recognize revenue from other collaboration agreements, including payments of upfront fees, license fees, milestone-based payments, and reimbursements for research and development efforts. As previously noted, we have executed a collaboration agreement with Kite and anticipate generating revenue under the arrangement subject to the total estimated transaction price as discussed in Note 6 - Collaboration Agreement in the notes to our condensed consolidated financial statements appearing in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Operating Expenses

Research and development expenses account for a significant portion of our operating expenses and consist primarily of external and internal costs incurred in connection with our CART-ddBCMA program, the development of our ARC-SparX product candidates, and the ongoing discovery and development efforts for additional product candidates.

External expenses include:

- Payments to third parties in connection with the clinical development of our product candidates, including contract research organizations (CROs) and consultants;
- The cost of manufacturing products for use in our preclinical studies and clinical trials, including payments to contract manufacturing organizations (CMOs) and consultants;
- Payments to third parties in connection with the preclinical development of our product candidates, including outsourced professional scientific development services, consulting research fees and for sponsored research arrangements with third parties;
- Laboratory supplies used in the preclinical development of our product candidates; and
- Allocated facilities, depreciation, and other expenses, which include direct or allocated expenses for IT, rent and maintenance of facilities.

Internal expenses include employee-related costs, including salaries, related benefits, and share-based compensation expense for employees engaged in research and development functions.

We expense research and development costs in the periods in which they are incurred. We track external costs on a program-by-program basis beginning with lead candidate selection. External costs that are not allocated to a program are classified as preclinical and discovery costs. We do not track internal costs by program because these costs are deployed across multiple programs, and as such, are not separately classified.

We have identified an embedded lease within the Lonza Manufacturing Services Agreement; under Amendment 1 to the Lonza SOW, we have the exclusive use of, and control over, the manufacturing facility and equipment of the supplier during the contractual term of the manufacturing arrangement. We have elected to use the practical expedient and account for the lease component and the non-lease components as a single lease component. Lease commencement occurred during 2022 when the applicable manufacturing facility and equipment became available for cGMP manufacturing under our exclusive use and control. In September 2023, the Company signed Amendment 1 to the Lonza SOW, allowing the Company to gain exclusive use and control over additional space and equipment.

Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages, primarily due to the increased size and duration of later-stage clinical trials. As a result, we expect that our research and development expenses will increase substantially in the foreseeable future as we continue to advance CART-ddBCMA through clinical

development, the regulatory approval process and, if approved, commercial launch activities; initiate or continue to advance our ARC-SparX product candidates, including expanding ACLX-001 and ACLX-002; continue to discover and develop additional product candidates to expand our pipeline; maintain, expand, protect, and enforce our intellectual property portfolio; and hire additional personnel.

The successful development of our product candidates is highly uncertain, and we do not believe it is possible at this time to accurately project the nature, timing, and estimated costs of the efforts necessary to complete the development of, and obtain regulatory approval for, any of our product candidates. To the extent our product candidates continue to advance into clinical trials, as well as advance into larger and later-stage clinical trials, our expenses will increase substantially and may become more variable. We are also unable to predict when, if ever, we will generate revenue from our product candidates to offset these expenses. 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 enrollment in, and completion of, clinical trials;
- Sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- Achieving favorable results from clinical trials;
- Receipt of marketing approvals from applicable regulatory authorities;
- Establishing and maintaining sufficient manufacturing capabilities, whether internally or with third parties, including securing raw material supply;
- Existence of, and our ability to identify, an addressable patient population for our product candidates;
- Effectively competing with other therapies;
- Maintaining a continued acceptable safety profile of any product following approval, if any;
- Submission of INDs or other regulatory applications for our planned clinical trials or future clinical trials and authorizations from regulators to initiate clinical trials;
- Identification of additional target antigens for desired indications;
- Identification and engineering of D-Domain-based binding regions that bind to the desired target antigens;
- Developing and implementing successful marketing and reimbursement strategies;
- Obtaining and maintaining patent, trade secret, and other intellectual property protection and regulatory exclusivity for our product candidates; and
- The market opportunities for certain of our product candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small, and our projections regarding the size of the addressable market may be incorrect.

Any changes in the outcome of any of these factors could significantly impact the costs, timing, and viability associated with the development of our product candidates and our ability to generate significant revenues from product sales.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, related benefits, and share-based compensation expense for personnel in executive, finance, and administrative functions. General and administrative expenses also include allocated facilities, depreciation, and other expenses, which include direct or allocated expenses for rent and maintenance of facilities and insurance, not otherwise included in research and development expenses, as well as professional fees for legal, patent, consulting, investor and public relations, accounting, and audit services.

We anticipate that our general and administrative expenses will increase as we increase our headcount to support the growth of the company. We further expect that our general and administrative expenses will increase substantially as we will incur substantially higher expenses relating to accounting, audit, legal, regulatory, compliance, director and officer insurance, and investor and public relations as a result of being a public company.

Other Income

Other income consists primarily of accretion of investments purchased at discounts, interest earned on our cash and cash equivalents, restricted cash, and marketable securities and interest expense related to our finance lease obligations.

Income Tax Provision

The Company has recorded an income tax expense of zero and $41 thousand for the three and nine months ended September 2023 respectively, and zero for the same periods in 2022.

Based on the available objective evidence during the three and nine months ended September 30, 2023, the Company believes it is more likely than not that the tax benefits of U.S. losses incurred during prior years may not be realized. Accordingly, the Company did not record the tax benefits of U.S. losses previously incurred as of September 30, 2023. The primary difference between the effective tax rate and the statutory tax rate relates to the valuation allowance on the Company's U.S. losses.

Results of Operations

Comparison of the Three Months Ended September 30, 2023 and 2022

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

	Three months ended September 30,		
	2023	**2022**	**Change**
Collaboration revenue	$ 14,957	$ —	$ 14,957
Operating expenses:			
Research and development	43,807	83,473	(39,666)
General and administrative	16,012	10,402	5,610
Total operating expenses	59,819	93,875	(34,056)
Loss from operations	(44,862)	(93,875)	49,013
Interest income, net	6,479	—	6,479
Interest expense	(959)	1,001	(1,960)
Other income, net	5,520	1,001	4,519
Loss before income taxes	(39,342)	(92,874)	53,532
Income tax benefit	6	—	6
Net loss	$ (39,336)	$ (92,874)	$ 53,538

Research and Development Expenses

Research and development expenses consist of the following (in thousands):

	Three months ended September 30,		
	2023	**2022**	**Change**
External costs:			
CART-ddBCMA	$ 28,374	$ 67,484	$ (39,110)
ACLX-001	637	2,379	(1,742)
ACLX-002	1,567	3,227	(1,660)
Other research and development costs	1,012	1,789	(777)
Total external costs	31,590	74,879	(43,289)
Internal costs	12,217	8,594	3,623
Total research and development expenses	$ 43,807	$ 83,473	$ (39,666)

Research and development expenses were $43.8 million for the three months ended September 30, 2023 compared to $83.5 million for the three months ended September 30, 2022, a decrease of $39.7 million. The decrease in research and development expense between periods is primarily attributable to the decrease in costs associated with our CART-ddBCMA clinical program, with such costs primarily relating to an expense for a related right of use asset associated with an embedded lease for our Lonza manufacturing services agreement for which there is no alternate use of $15.9 million and $63.1 million respectively, for the three months ended September 30, 2023 and 2022. The increase in internal costs of $3.6 million is primarily due to higher personnel-related costs of $2.1 million and higher facility and equipment costs of $1.5 million for the three months ended September 30, 2023 as compared to the three months ended September 30, 2022.

General and Administrative Expenses

General and administrative expenses were $16.0 million for the three months ended September 30, 2023 compared to $10.4 million for the three months ended September 30, 2022, an increase of $5.6 million. This was primarily due to an increase of $4.1 million in personnel-related costs primarily consisting of a $4.0 million increase in stock-based compensation and an increase of $0.9 million in professional fees related to consulting, legal, accounting and audit services.

Comparison of the Nine Months Ended September 30, 2023 and 2022

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

	Nine Months Ended September 30,		
	2023	2022	Change
Collaboration revenue	$ 47,171	$ —	$ 47,171
Operating expenses:			
Research and development	105,065	123,612	(18,547)
General and administrative	46,985	27,643	19,342
Total operating expenses	152,050	151,255	795
Loss from operations	(104,879)	(151,255)	46,376
Interest income, net	17,251	—	17,251
Interest expense	(2,865)	1,568	(4,433)
Other income, net	14,386	1,568	12,817
Loss before income taxes	(90,493)	(149,687)	59,194
Income tax expense	(41)	—	(41)
Net loss	$ (90,534)	$ (149,687)	$ 59,153

Research and Development Expenses

Research and development expenses consist of the following (in thousands):

	Nine Months Ended September 30,		
	2023	2022	Change
External costs:			
CART-ddBCMA	$ 62,229	$ 84,597	$ (22,368)
ACLX-001	1,999	6,449	(4,450)
ACLX-002	3,936	5,620	(1,684)
Other research and development costs	2,704	4,287	(1,583)
Total external costs	70,868	100,953	(30,085)
Internal costs	34,197	22,659	11,538
Total research and development expenses	$ 105,065	$ 123,612	$ (18,547)

Research and development expenses were $105.1 million for the nine months ended September 30, 2023 compared to $123.6 million for the nine months ended September 30, 2022, a decrease of $18.5 million, primarily related to the Company's multiple myeloma program, CART-ddBCMA. The decrease in CART-ddBCMA expense of $22.4 million between periods is primarily attributable to the decrease in the expense for a leased asset with no alternate use of $44.9 million compared to prior year. The decrease in CART-ddBCMA expense from the leased asset is offset by an increase of $22.5 million in other external CART-ddBCMA costs for the nine months ended September 30, 2023 when compared to the nine months ended September 30, 2022. The increase in internal costs of $11.5 million is primarily due to higher personnel-related costs of $7.0 million and higher facility and equipment costs of $3.3 million for the nine months ended September 30, 2023 as compared to the nine months ended September 30, 2022. The decrease in ACLX-001 costs in mainly due to decrease in external related costs when compared to the nine months ended September 30, 2022.

General and Administrative Expenses

General and administrative expenses were $47.0 million for the nine months ended September 30, 2023 compared to $27.6 million for the nine months ended September 30, 2022, an increase of $19.4 million. This was primarily due to an increase of $14.8 million in personnel-related costs primarily consisting of a $12.5 million increase in stock-based compensation and an increase of $2.1 million in professional fees related to consulting, legal, accounting and audit services.

Liquidity and Capital Resources

Since inception, we have incurred net losses and negative cash flows from operations and we expect to incur substantial additional losses in future periods. As of September 30, 2023, we had cash and cash equivalents and marketable securities of $482.7 million. As of the date of filing this Quarterly Report on Form 10-Q, we have access to and control over all our cash, cash equivalents, and marketable securities.

To date, we have not generated any product revenue. We do not expect to generate any meaningful revenue from product sales unless and until we obtain regulatory approval of, and commercialize any of, our product candidates, except that our collaboration agreement with Kite will yield revenue up to the total estimated transaction price. We may also enter into other collaborative agreements with third parties, and we do not know when, or if, any will occur. We expect to continue to incur significant losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our product candidates and begin to commercialize any approved products. We are subject to all of the risks typically related to the development of new product candidates, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. Moreover, we expect to incur additional costs associated with operating as a public company, particularly relating to our pending loss of EGC and smaller reporting company status. Adequate funding may not be available to us on acceptable terms or at all.

Based on our expected operating cash requirements and capital expenditures, we believe our current cash and cash equivalents and investments in marketable securities are adequate to fund operations into 2026.

Cash Flows

The following table sets forth a summary of the primary sources and uses of cash for each of the periods presented below (in thousands):

	Nine Months Ended September 30,	
	2023	2022
Net cash provided by (used in) operating activities	$ 149,325	$ (71,783)
Net cash used in investing activities	(175,529)	(151,296)
Net cash provided by financing activities	90,572	251,311
Net increase in cash, cash equivalents, and restricted cash	$ 64,368	$ 28,232

Operating Activities

Net cash provided by operating activities during the nine months ended September 30, 2023 of $149.3 million was primarily attributable to our net loss of $90.5 million and amortization of premiums and discounts on marketable securities of $7.1 million offset by changes in operating assets and liabilities of $195.4 million and an adjustment for non-cash share-based compensation expense and right-of-use asset expense of $31.2 million and $18.2 million respectively.

Net cash used in operating activities during the nine months ended September 30, 2022 of $71.8 million was primarily attributable to our net loss of $149.7 million and net changes in operating assets and liabilities of $2.3 million, partially offset by non-cash charges for right of use asset expensed of $63.1 million, share-based compensation expense of $15.8 million, and depreciation and amortization expense of $0.9 million.

Investing Activities

Net cash used in investing activities of $175.5 million during the nine months ended September 30, 2023 was attributable to $400.0 million in purchases of marketable securities and $16.1 million in purchases of property and equipment, offset by proceeds from maturities of marketable securities of $240.7 million.

Net cash used in investing activities of $151.3 million during the nine months ended September 30, 2022 was attributable to $150.3 million in net purchases of marketable securities.

Financing Activities

Net cash provided by financing activities of $90.6 million during the nine months ended September 30, 2023 was primarily attributable to net proceeds of $100.0 million from the issuance and sale of 3,478,261 shares of our common stock at $28.75 per share and the proceeds of $4.6 million from the exercise of stock options and proceeds from stock issued pursuant to the employee stock purchase plan, offset by payments under finance leases totaling $14.0 million.

Net cash provided by financing activities of $251.3 million during the nine months ended September 30, 2022 was primarily attributable to net proceeds of $129.2 million from the issuance of common stock as part of our IPO, net proceeds of $10.0 million from the issuance of common stock as part of a private placement, net proceeds of $121.5 million from the issuance of common stock as part of our follow-on public offering, offset by $9.3 million in finance lease payments.

Contractual Obligations and Contingencies

As of September 30, 2023, there have been no material changes from the contractual obligations and commitments previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2022 except for our minimum non-cancellable costs payable to Lonza, which at September 30, 2023 was approximately $58.4 million.

Critical Accounting Policies and Estimates

Our condensed consolidated financial statements are prepared in accordance with generally accepted accounting principles (GAAP) in the United States. The preparation of our condensed consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our condensed consolidated financial statements. We base our estimates on historical experience, known trends and events, and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on a periodic basis. Our actual results may differ from these estimates.

Critical accounting estimates are those estimates made in accordance with GAAP that involve a significant level of estimation uncertainty and have had or area reasonably likely to have a material impact on our financial condition or results of operations. For a summary of our critical accounting policies and estimates, refer to Part II, Item 7 — Management's Discussion and Analysis of Financial Condition and Results of Operations of our Annual Report on Form 10-K for the year ended December 31, 2022. There have been no material changes to our critical accounting policies and estimates during the nine months ended September 30, 2023 except for those relating to Revenue and Income Taxes disclosed in Note 2 to our condensed consolidated financial statements appearing in Part I, Item 1 of this Quarterly Report on Form 10-Q and disclosed below.

Revenue Recognition

We assess whether our collaboration agreements are subject to Accounting Standards Codification (ASC) Topic 808, Collaborative Arrangements (ASC 808) based on whether they involve joint operating activities and whether both parties have active participation in the arrangement and are exposed to significant risks and rewards that depend on the commercial success of the joint operation activities. To the extent that the arrangement falls within the scope of ASC 808, we apply the unit of account guidance under ASC Topic 606, Revenue from Contracts with Customers (ASC 606), to identify distinct performance obligations, and then determine whether a customer relationship exists for each distinct performance obligation. If we determine whether a promised good or service within the arrangement is with a customer, we apply the guidance in ASC 606. If a portion of a distinct bundle of goods or services within an arrangement is not with a customer, then the unit of account is not within the scope of ASC 606, and the recognition and measurement of that unit of account shall be based on analogy to authoritative accounting literature or, if there is no appropriate analogy, a reasonable, rational, and consistently applied accounting policy election.

We recognize revenue when a customer obtains control of promised goods or services in a contract for an amount that reflects the consideration we expect to receive in exchange for those goods or services. For contracts with customers, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy each performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. As part of the accounting for contracts with customers, we must develop assumptions that require judgment to determine the standalone selling price of each performance obligation identified in the contract. We then allocate the total transaction price to each performance obligation based on their estimated standalone selling prices. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

If the consideration promised in a contract includes a variable amount, we estimate the amount of consideration to which we will be entitled in exchange for transferring the promised goods or services to a customer. We determine the amount of variable consideration by using the expected value method or the most likely amount method. We include the unconstrained amount of estimated variable consideration in the transaction price. The amount included in the transaction price is the amount for which it is probable that a significant reversal of cumulative revenue recognized will not occur. At the end of each subsequent reporting period, we re-evaluate the estimate of variable consideration included in the transaction price and any related constraint, and if necessary,

adjust our estimate of the overall transaction price. Variable consideration, such as milestone payments and consideration paid or payable to a collaboration partner, must be evaluated to determine if it is constrained and, therefore, excluded from the transaction price. Any such adjustments are recorded on a cumulative catch-up basis in the period of adjustment.

The accounting for these arrangements requires us to develop estimates and assumptions that require judgment to determine the underlying stand-alone selling price for each performance obligation, which determines how the transaction price is allocated among the performance obligations. These estimates may include items such as forecasted revenues or costs, development timelines, discount rates, and probabilities of technical and regulatory success. We evaluate each performance obligation to determine if it is satisfied at a point in time or over time. For performance obligations satisfied over time, we determine the appropriate measure of progress. The effect of any change made to the measure of progress and, therefore a change to revenue, would be recorded as a change in estimate.

Our collaborative arrangements can have one or more of the following forms of consideration: (i) license fees; (ii) milestone payments related to the achievement of developmental, regulatory, or commercial goals; (iii) royalties on net sales of licensed products; (iv) fees attributable to options to intellectual property; (v) cost-sharing or research and development (R&D) funding arrangements and (vi) profit and loss sharing. When a portion of non-refundable upfront fees or other payments received are allocated to continuing performance obligations under the terms of a collaborative arrangement, they are recorded as contract liabilities and recognized as revenue when (or as) the underlying performance obligation is satisfied. We classify contract liabilities as current when we expect to satisfy our performance obligations within one year, and noncurrent when we expect to satisfy those performance obligations in greater than one year. Fees attributable to options are deferred until the option expires or is exercised. Changes to collaboration agreements are assessed for whether they represent a modification or should be accounted for as a new contract.

Upfront Payments and License Fees

If a license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenues from non-refundable, upfront fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

Variable Consideration

Variable consideration is assessed at each reporting period as to whether it is not subject to future reversal of cumulative revenue and, therefore, should be included in the transaction price. Assessing the recognition of variable consideration requires judgment. Consideration paid or payable to a collaboration partner is estimated and included in the total transaction price. Variable consideration is included in the transaction price when the Company concludes that it is probable that a significant revenue reversal will not occur in future periods. Actual amounts of consideration ultimately received may differ from the Company's estimates.

Cost-sharing

Under certain collaborative arrangements, the Company can be reimbursed for a portion of its research and development expenses or reimburse its collaboration partner for its research and development expenses. The Company estimates reimbursements to be received by a collaboration partner and reimbursements to be paid or payable to a collaboration partner as part of variable consideration. When these research and development services are paid to a collaboration partner, the Company reduces its contract liability.

Customer Options

Customer options, such as options granted to allow a licensee to extend a license or research term, to select additional research targets or to choose to research, develop and commercialize licensed compounds are evaluated at contract inception to determine whether those options provide a material right (i.e., an optional good or service offered for free or at a discount) to the customer. If the customer options represent a material right, the material right is treated as a separate performance obligation at the outset of the arrangement. We allocate the transaction price to material rights based on the standalone selling price. As a practical alternative to estimating the standalone selling price of a material right when the underlying goods or services are both (i) similar to the original goods or services in the contract and (ii) provided in accordance with the terms of the original contract, we allocate the total amount of consideration expected to be received from the customer to the total goods or services expected to be provided to the customer. Amounts allocated to any material right are recognized as revenue when or as the related future goods or services are transferred or when the option expires.

Milestone Payments

At the inception of the arrangement, we evaluate whether the development or sales-based milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated value is included in the transaction price. Milestone payments that are not within our control or that of our collaboration partner, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received. At the end of each subsequent reporting period, we re-evaluate the probability of achievement of such development or sales-based milestones and any related constraint, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would revenues in the period of adjustment.

We may earn milestones through achievement of pre-specified developmental or regulatory events and, as such, milestones are accounted for as variable consideration. Under the agreement currently in place, we do not consider these events to be within our control, but rather dependent upon the development activities of our collaborative partner and the decisions made by regulatory agencies. Accordingly, these milestones are not included in the transaction price until the counterparty, or third-party in the event of a regulatory submission, confirms the satisfaction or completion of the milestone triggering event. Given the high level of uncertainty of achievement, variable consideration associated with milestones are fully constrained. The value of these milestones is dictated within the contract and is fixed upon achievement and reflects the amount of consideration which we expect to be entitled to in exchange for the satisfaction of that milestone. The process of successfully discovering a new development candidate, having it approved and successfully commercialized is highly uncertain. As such, the milestone payments we may earn from our partners involve a significant degree of risk to achieve and therefore, subsequent milestone payments due us are recognized as revenue at the point in time when such milestones are achieved. For milestone revenues related to sales-based achievements, we recognize the milestone revenues in the corresponding period of the product sale, in accordance with the guidance of ASC 606-10-55-65 for contracts that include a license to intellectual property and the license is the predominant item to which the product sale relates.

Royalties

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and for which the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, we have not recognized any royalty revenue resulting from its collaborative arrangement.

The timing of revenue recognition and contract billings may differ and result in contract assets and contract liabilities. Contract assets represent revenues recognized in excess of amounts billed under collaboration agreements and are transferred to accounts receivable when billed or billing rights become unconditional. Contract liabilities represent billings in excess of revenues recognized under collaboration agreements.

Income taxes

We account for income taxes in accordance with ASC 740-10. Deferred tax assets and liabilities are recognized to reflect the estimated future tax effects, calculated at the tax rate expected to be in effect at the time of realization. A valuation allowance related to a deferred tax asset is recorded when it is more likely than not that some portion of the deferred tax asset will not be realized. Deferred tax assets and liabilities are adjusted for the effects of the changes in tax laws and rates of the date of enactment. ASC 740-10 prescribes a recognition threshold that a tax position is required to meet before being recognized in the financial statements and provides guidance on recognition, measurement, classification, interest and penalties, accounting in interim periods, disclosure and transition issues. Interest and penalties are classified as a component of interest and other expenses. To date, we have not been assessed, nor paid, any interest or penalties. Uncertain tax positions are measured and recorded by establishing a threshold for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Only tax positions meeting the more-likely-than-not recognition threshold at the effective date may be recognized or continue to be recognized. We continue to maintain a full valuation allowance for our net deferred tax assets. Income tax expense for the nine months ended September 30, 2023 relates to the revenue being recognized from the Kite Collaboration Agreement as discussed in Note 6 of these condensed consolidated financial statements included elsewhere in this report.

Emerging Growth Company and Smaller Reporting Company Status

We are currently an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (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 that those standards apply to private companies. We have 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 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 the new or revised accounting pronouncements as of public company effective dates.
An emerging growth company may take advantage of specified reduced reporting requirements and is relieved of certain other significant requirements that are otherwise generally applicable to public companies. As an emerging growth company:

- we may avail ourselves of the exemption from the requirement to obtain an attestation and report from our auditors on the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act;
- we may provide reduced disclosure about our executive compensation arrangements; and
- we may not require stockholder non-binding advisory votes on executive compensation or golden parachute arrangements.

We have elected to take advantage of certain of the reduced disclosure and reporting requirements in this Quarterly Report on Form 10-Q. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

We are also currently a smaller reporting company. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited consolidated financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

On the last business day of the second quarter in 2023, the aggregate market value of the Company's shares of common stock held by non-affiliate stockholders exceeded $700 million. As a result, as of December 31, 2023, the Company will be considered a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, and will cease to be an EGC. As a result, among other things, the Company will no longer be exempt from the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, and our independent registered public accounting firm will evaluate and report on the effectiveness of internal control over financial reporting. The Company will adopt any accounting pronouncements deferred under the extended transition period election on or before December 31, 2023.

Effective December 31, 2023, due to large accelerated filer status, the Company will also no longer be permitted to take advantage of reduced reporting requirements for smaller reporting companies, subject to a transition period that allows for the Company to use smaller reporting company scaled disclosure for the Company's Annual Report on Form 10-K for the year ending December 31, 2023.

Recent Accounting Pronouncements

A description of recently issued and adopted accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our consolidated financial statements appearing in the Annual Report on Form 10-K for the year ended December 31, 2022 and in the notes to our condensed consolidated financial statements appearing in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

As a smaller reporting company, we are not required to provide the information required by this Item.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures are designed to provide reasonable assurance that the information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods set forth in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing disclosure controls and procedures, management recognizes that any control system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the control system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

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

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in litigation or other legal proceedings. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors.

Our business and industry are subject to significant risks. You should carefully consider the risks described below, as well as the other information in this Quarterly Report on Form 10-Q, including our condensed consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in Part II, Item 7, before deciding whether to invest in our common stock. The occurrence of any of the events or developments described in the following risk factors and the risks described elsewhere in this report could seriously harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline and you may lose all or part of your investment. The risks described below are not guarantees that no such conditions exist as of the date of this report and should not be interpreted as an affirmative statement that such risks or conditions have not materialized, in whole or in part. 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 factors that are described below and elsewhere in this Quarterly Report on Form 10-Q. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

Risk Factor Summary

Our ability to execute our business strategy is subject to numerous risks, as more fully described in the section immediately following this summary. These risks include, among others:

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

•We have a limited operating history and have incurred significant losses since our inception, and we anticipate that we will continue to incur losses for the foreseeable future, which makes it difficult to assess our future viability.

•We will need substantial additional funding. If we are unable to raise capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and development programs, future commercialization efforts or employee headcount.

Risks Related to Development of Our Product Candidates

•In June 2023, the FDA issued a partial clinical hold on CART-ddBCMA. Although the FDA has lifted its partial clinical hold, there is no assurance that the protocol amendments we have made will be effective at mitigating the risk of future serious adverse events or that the FDA or DSMB will not issue another clinical hold in the future resulting in the suspension or halting of our clinical study.

•Our product candidates are in the early stages of development. We have no products approved for commercial sale and have only recently begun clinical trials to test our first product candidates in humans, which may make it difficult for you to evaluate our current business and predict our future success and viability.

•Our ddCAR and ARC-SparX platforms represent novel and unproven approaches to treatment, which makes it difficult to predict the timing, results and costs of product candidate development and the likelihood of obtaining regulatory approval. In addition, we may experience difficulty in identifying appropriate target binding domains.

•Our ARC-SparX platform is highly dependent on the success of both ACLX-001 and ACLX-002.

•Clinical development is a lengthy, expensive and uncertain process. Our clinical trials may fail to demonstrate adequate safety and/or efficacy of any of our product candidates.

•We may encounter substantial delays, including difficulties enrolling patients, in our clinical trials.

•Our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, require expansion of the trial size, limit their commercial potential, or result in significant negative consequences.

•Interim, preliminary or topline data from our clinical trials that we announce or publish from time to time may change as more patient data become available.

•Manufacturing genetically engineered products is complex and subject to both human and systemic risks. We or our third-party manufacturers may encounter difficulties in production and sourcing and may be subject to variations and supply constraints of key components. Modifications in manufacturing may require additional studies and regulatory filings, resulting in additional costs or delay.

•We are subject to regulatory standards and requirements imposed by FDA in the regulatory approval process, which can be lengthy, time-consuming and inherently unpredictable, and may result in significant delays in clinical development or inability to commercialize our product candidates.

•We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

Risks Related to Our Business

•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 expect to grow the size of our organization, and we may experience difficulties in managing this growth.

•We may become exposed to costly and damaging product liability claims, either when testing our product candidates in the clinic or at the commercial stage, and our product liability insurance may not cover all damages from such claims.

•Our business may be affected by lasting effects of the COVID-19 pandemic on the drug development industry and may be significantly adversely affected if other events out of our control disrupt our business or that of our third-party providers.

Risk Related to Reliance on Third Parties

•We rely and will rely on third parties to conduct our clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.

•We rely and expect to continue to rely on third parties to manufacture our clinical product supplies and clinical candidates, and we may rely on third parties for at least a portion of the manufacturing process of our product candidates, if approved. Our business could be harmed if those third parties fail to provide us with sufficient quantities of product supplies or product candidates or fail to do so at acceptable quality levels or prices or if we terminate our relationship for any reason including due to a change in ownership, operating strategy or financial standing.

•We depend on Kite for certain development and commercialization activities with respect to certain of our product candidates pursuant to our collaboration with Kite. If such collaboration is not successful, we may not be able to realize the market potential of those product candidates.

Risks Related to Our Intellectual Property

•If we are unable to obtain and maintain sufficient intellectual property protection for our platforms and our 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.

•Third-party claims of intellectual property infringement may prevent or delay our product discovery and development efforts.

Risks Related to Government Regulation

•We may be unable to obtain regulatory approval for our product candidates. The denial or delay of any such approval would delay commercialization and have a material adverse effect on our potential to generate revenue, our business and our results of operations.

•We will face increasing regulation as we advance our product candidates through clinical trials and pursue commercialization, if approved.

Risks Related to Commercialization of Our Product Candidates

•Even if we obtain regulatory approval of our product candidates, the products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers and others in the medical community.

Risks Related to Ownership of our Common Stock

•The price of shares of our common stock may be volatile and may be adversely impacted by future events, and you could lose all or part of your investment.

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

We have a limited operating history and have incurred significant losses since our inception, and we anticipate that we will continue to incur losses for the foreseeable future, which makes it difficult to assess our future viability.

We are a clinical-stage biopharmaceutical company with a limited operating history. 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 D-Domain, ddCAR and ARC-SparX technologies, identifying potential new target antigens, developing product candidates and undertaking research and development, including preclinical studies and clinical trials of our product candidates, all of which are biologics or biopharmaceuticals and require approval under a Biologics License Application ("BLA"). We have not yet demonstrated our ability to successfully complete any large-scale or pivotal clinical trials, obtain marketing approvals, manufacture commercial-scale product, or conduct sales and marketing activities necessary for successful product commercialization. As a result, it may be more difficult for you to accurately predict our future success or viability than it could be if we had a longer operating history or were closer to commercialization. In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges that may adversely affect our business.

We have no products approved for commercial sale and have not generated any revenue from product sales, and we continue to incur significant research and development and other expenses related to our ongoing operations. We have incurred losses in each period since our inception in December 2014. Our net losses were $90.5 million for the nine months ended September 30, 2023. As of September 30, 2023, we had an accumulated deficit of $409.3 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we advance our product candidates through preclinical studies and clinical trials; continue to discover and develop additional product candidates and expand our pipeline; continue to develop our D-Domain, ddCAR and ARC-SparX platforms; maintain, expand, protect and enforce our intellectual property portfolio; and hire additional personnel. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate meaningful revenue from product sales, which we do not expect will occur in the foreseeable future, as our product candidates are in preclinical or early clinical development. Our prior and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We will need to obtain substantial additional funding to complete the development of our product candidates.

Investment in biopharmaceutical product development is highly risky because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. 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, whether internally or with third-party partners and collaborators and advance our product candidates through preclinical studies and clinical trials in order to obtain marketing approval. If we obtain marketing approval for any of our product candidates, we also expect to incur significant commercialization expenses related to marketing, sales, manufacturing and distribution. Furthermore, we will continue to incur additional costs associated with operating as a public company.

Based on our current operating plan, we believe that our existing cash, cash equivalents, and marketable securities will be sufficient to fund our planned operations for at least the next twelve months, but our assumptions could prove to be wrong, and we could consume capital significantly faster than we expect, requiring us to seek additional funding sources sooner than planned, through public or private financings or other sources, such as strategic collaborations. Such financing may result in dilution to stockholders, the imposition of burdensome debt covenants and repayment obligations or other restrictions that may affect our business. Our future capital requirements will depend on many factors, including:

- The scope, progress, timing, results and costs of developing and manufacturing our product candidates, and their components, and conducting preclinical studies and clinical trials and other testing of our product candidates;
- Our ability to continue our business operations and product candidate research and development, and to adapt to any changes in the regulatory approval process, manufacturing supply, or clinical trial requirements and timing relating to the COVID-19 pandemic or otherwise;
- The costs, timing and outcome of regulatory review of any of our product candidates;
- The costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims, including any claims by third parties that we are infringing upon their intellectual property rights;
- Our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;

•The costs and timing of future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;

•The extent to which our product candidates, if approved, can be offered by prescribers in various clinical settings, including academic hospitals and community practices, the acceptance of our products, if and when approved, by patients, the medical community and third-party payors, and the revenue received from commercial sale of any products for which we receive marketing approval;

•The effect of competing technologies and market developments; and

•The extent to which we acquire or invest in other businesses, products and technologies and any other licensing or collaboration arrangements for any of our product candidates.

We cannot be certain that additional funding will be available on acceptable terms, or at all (as further described under Risks Related to Our Business). If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to decrease headcount and/or significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives. We could be required to seek collaborators for our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable to us than might otherwise be available or relinquish or license on unfavorable terms our rights to our product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves. Any of the foregoing events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

In addition, we may seek additional capital due to strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop our product candidates.

We identified a material weakness in our internal control over financial reporting in the quarter ending September 30, 2022, which was remediated as of December 31, 2022. Any future material weakness identified may adversely affect our business, reputation and stock price.

During the quarter ended September 30, 2022, our management and Audit Committee concluded that we had a material weakness in our internal control over financial reporting relating to accounting for research and development expenses and related accounts. The effects of errors in such accounting resulted in an overstatement of research and development expenses, resulting in a restatement of the condensed consolidated financial statements contained in our Quarterly Reports on Form 10-Q for each of the periods ended March 31, 2022 and June 30, 2022, as management determined that the aggregate effect of the individual errors in each period was material to the condensed consolidated financial statements for such fiscal quarters. See Part II, Item 9A “Control and Procedures” in our Form 10-K that was filed March 29, 2023 for more information about the material weakness that we identified; the material weakness was remediated as of December 31, 2022.

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 financial statements will not be prevented or detected on a timely basis. Any material weakness(es) that we identify in the future will not be considered remediated until management designs and implements effective controls that operate for a sufficient period of time and management has concluded through testing that such controls are effective. We cannot provide any assurances that the measures that we may take will be sufficient to remediate any such material weakness or prevent future material weaknesses from occurring. While we have remediated the material weakness that we identified, we cannot assure you that we have identified all of our existing material weaknesses.

The material weakness and ineffective internal financial and accounting controls and procedures we identified, though remediated, could nevertheless cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock. In the event we identify an additional material weakness in the future, such an additional material weakness could adversely impact our ability to report our financial results on a timely basis and could likewise cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

Risks Related to Development of Our Product Candidates

Our product candidates are in the early stages of development. We have no products approved for commercial sale and have only recently begun clinical trials to test our first product candidates in humans, which may make it difficult for you to evaluate our current business and predict our future success and viability.

We are early in our development efforts. We are still developing our D-Domain, ddCAR and ARC-SparX platforms, and conducting drug discovery and preclinical studies for a number of product candidates while advancing our ongoing clinical trials for CART-ddBCMA, ACLX-001 and ACLX-002. We have treated a small number of patients as of the date hereof and our clinical

experience with our initial product candidates is limited. Because our product candidates are in the development stage, there is a high risk of failure and we may never succeed in developing marketable products. In addition, regulatory delays or rejections may be encountered as a result of many factors, including changes in regulatory policy and/or feedback during the period of product development.

There is a high failure rate for biopharmaceutical products proceeding through clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in later stage clinical trials even after achieving promising results in earlier stage clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. For example, a large percentage of the patients enrolled in the Phase 1 CART-ddBCMA trial had poor prognostic factors associated with increased tumor burden and may have impacted our rates of response. We therefore believe that the pivotal trial may yield improved PFS rates and retain a comparable safety profile to the Phase 1 trial if the pivotal trial enrolls a population with fewer poor prognostic features. However, the resulting enrolled patient population of the pivotal trial could be different than expected, these prognostic factors may not have as significant of an impact as we had expected, or there may be other factors that have greater impact on the rate of response, among other risks.

In June 2023, the FDA issued a partial clinical hold on CART-ddBCMA following a recent patient death. Although the FDA has lifted its partial clinical hold, there is no assurance that the FDA will not issue another clinical hold in the future. Addressing a clinical hold takes considerable time and expense and there can be no assurance that the FDA will remove a clinical hold in a timely manner, or at all, in which case our business and prospects for development and approval of CART-ddBCMA would be materially harmed.

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:

•Identification of additional target antigens for desired indications;

•Identification and development of D-Domain-based binding regions that bind to the desired target antigens;

•Successful completion of preclinical studies;

•Submission of INDs or other regulatory applications for our planned clinical trials or future clinical trials and authorizations from regulators to initiate clinical trials;

•Successful enrollment in, and completion of, clinical trials;

•Achieving favorable results from clinical trials;

•Receipt of marketing approvals from applicable regulatory authorities;

•Establishing and maintaining sufficient manufacturing capabilities, whether internally or with third parties, for clinical and commercial supply, including procurement of raw materials;

•Establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in combination with other products;

•Sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials and commercialization activities;

•Effectively competing with other therapies;

•Developing and implementing successful marketing and reimbursement strategies;

•Obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity for our product candidates; 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.

We cannot be certain that our clinical trials will be initiated and completed on time, if at all, or whether our planned clinical strategy will be acceptable to the FDA or foreign health authorities. In addition, it remains difficult to predict the lasting impact the COVID-19 pandemic may have on the development of our product candidates, our preclinical studies and clinical trials, and our business.

To become and remain profitable, we must develop, obtain approval for and eventually commercialize products, if approved, that generate significant revenue. We do not expect to receive approval of any product candidates for many years and may never

succeed in these activities. In addition, it is not uncommon for product candidates to exhibit unforeseen safety issues or inadequate efficacy when tested in humans despite promising results in preclinical animal models or earlier trials, and we may ultimately be unable to demonstrate adequate safety and efficacy of our product candidates to obtain marketing approval. Even if we obtain approval and begin commercializing one or more of our product candidates, we may never generate revenue that is significant or large enough to achieve profitability.

Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development, manufacturing and other expenditures to develop and market additional product candidates. Our failure to become or remain profitable would decrease the value of the company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations.

Our ddCAR and ARC-SparX platforms represent novel and unproven approaches to treatment, which makes it difficult to predict the timing, results and costs of product candidate development and the likelihood of obtaining regulatory approval. In addition, we may experience difficulty in identifying appropriate target binding domains.

We have concentrated our research and development efforts on our ddCAR and ARC-SparX platforms, and our future success depends on the successful development of these platforms. Although there are other cell therapies and adapter platforms in clinical development, our platform technologies, including our D-Domain technology, have not been extensively tested over any significant period of time. In addition, while we believe that our platforms may be capable of overcoming certain challenges faced by conventional CAR-T therapies, we cannot be certain that our approach will result in the intended benefits or will not result in unforeseen negative consequences over time. As an example, we may not be able to identify D-Domain binders that can recognize certain antigen targets that we would like to pursue, or the development of the applicable D-Domain, ddCAR or SparX protein targeting such antigens may be too challenging or expensive to be commercially viable. We do not currently have any approved or commercialized products. As with other targeted therapies, off-tumor or off-target activity could delay development or require us to re-engineer or abandon a particular product candidate. There can be no assurance that any problems we experience in the future related to preclinical and clinical development of our novel platforms and our product candidates will not cause significant delays or unanticipated costs or that such problems can be solved. We may also experience delays in developing sustainable, reproducible and scalable manufacturing processes or transferring those processes to manufacturing partners or developing our own internal manufacturing capabilities, which may prevent us from completing our clinical trials or successfully commercializing our product candidates on a timely or profitable basis, if at all.

Because cell therapies represent a relatively new field of cellular immunotherapy and cancer treatment generally, developing and commercializing our product candidates subjects us to a number of risks and challenges, including:

- Developing and deploying consistent and reliable processes for procuring a patient's apheresis material, engineering a patient's T-cells ex vivo and infusing the engineered T-cells back into the patient;
- Developing protocols for the safe administration of our product candidates, including identifying appropriate patients and setting sufficient risk mitigation and adverse event management measures and safeguards;
- Establishing integrated solutions in collaboration with specialty treatment centers and other clinical settings in order to reduce the burdens and complex logistics commonly associated with the administration of T cell therapies;
- Conditioning patients with chemotherapy in conjunction with delivering each of our products, which may increase the risk of adverse side effects of our product candidates;
- Educating medical personnel about the administration of our product candidates, particularly if our clinical trials permit expansion of participating physicians to those in various clinical settings;
- Educating medical personnel regarding the potential efficacy and safety profiles of our product candidates, as well as the challenges, of incorporating our product candidates, if approved, into treatment regimens;
- Sourcing, supplies for the materials used to manufacture and process our product candidates for clinical trials and, in the future, commercial sale, if our product candidates are approved;
- Developing reliable and scalable manufacturing processes;
- Establishing adequate manufacturing capacity suitable for the manufacture of our product candidates in line with expanding enrollment in our clinical trials and our projected commercial requirements;
- Achieving cost efficiencies in the scale-up of our manufacturing capacity;
- Obtaining and maintaining regulatory approval from the FDA or other health authorities;

•Establishing sales and marketing capabilities to successfully launch and commercialize our product candidates if and when we obtain any required regulatory approvals, and risks associated with gaining market acceptance of novel therapies if we receive approval; and

•Obtaining coverage and adequate reimbursement from third-party payors for our novel therapies in connection with commercialization of any approved product candidates.

We may not be able to successfully develop our product candidates, our technology or our other product candidates in a manner that will yield products that are safe, effective, scalable or profitable. Additionally, because our technology involves the genetic modification of patient T-cells ex vivo, we are subject to additional regulatory challenges and risks, including:

•Regulatory requirements governing gene and cell therapy products have changed frequently and may continue to change in the future;

•Genetically modified products in the event of improper insertion of a gene sequence into a patient's chromosome could lead to lymphoma, leukemia or other cancers, or other aberrantly functioning cells;

•Although our viral vectors are not able to replicate, there is a risk with the use of lentiviral vectors that they could lead to new or reactivated pathogenic strains of virus or other infectious diseases; and

•The FDA recommends a 15-year follow-up observation period for all patients who receive treatment using gene therapies, and we may need to adopt such an observation period for our product candidates.

Moreover, public perception and awareness of cell therapy safety issues may adversely influence the willingness of subjects to participate in clinical trials of our product candidates, or if approved, of physicians to prescribe our products. Physicians, hospitals and third-party payors often are slow to adopt new products, technologies and treatment practices that require additional upfront costs and training. Treatment centers may not be willing or able to devote the personnel and establish other infrastructure required for the administration of CAR-T cell therapies. Physicians may not be willing to undergo training to adopt this novel and personalized therapy, may decide the therapy is too complex to adopt without appropriate training and may choose not to administer the therapy. Based on these and other factors, hospitals and payors may decide that the benefits of this new therapy do not or will not outweigh its costs.

Additionally, in developing our product candidates, we have not exhaustively explored different options in the design and method for manufacturing ddCARs, ARC-T-cells and SparX proteins. Although we do not currently plan to change the structure of our ddCARs, ARC-T-cells or SparX proteins in the near term, we may in the future find our ddCARs, ARC-T-cells or SparX proteins, or any manufacturing process thereof, may be substantially improved with future design or process changes. Changes in product design and changes in the manufacturing process, equipment, or facilities may require further comparability analysis and approval by FDA before implementation, which could delay our clinical trials and product candidate development, and could require additional clinical trials, including bridging studies, to demonstrate consistent and continued safety, identity, purity and efficacy. For example, we have used a lentiviral vector to transduce the gene for the ddCAR and ARC constructs into patient T-cells. In the future, we may find that another type of vector or other means of genetically modifying T-cells may offer advantages, particularly as we consider inserting our ddCARs and ARC-T-cells into other immune cells. Changing how we genetically modify the immune cells would necessitate additional process development, comparability studies, regulatory filings and clinical testing and delay existing product candidates.

In addition, the clinical trial requirements of the FDA and foreign health authorities and the criteria these regulators use to determine whether a product candidate is acceptable for approval, can vary substantially according to the type, complexity, novelty and intended use and market of the potential products. While CAR-T and other cell 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.

Our ARC-SparX platform is highly dependent on the success of both ACLX-001 and ACLX-002.

Our ARC-SparX platform, including our AML/MDS program, is highly dependent on the success of ACLX-001 and ACLX-002, the first two product candidates based on our ARC-SparX platform. ACLX-001 is an immunotherapeutic combination composed of ARC-T-cells and bi-valent SparX proteins targeting BCMA, or SPRX001, for the treatment of rrMM. ACLX-002 is an immunotherapeutic combination composed of ARC-T-cells and monovalent SparX proteins targeting CD123, or SPRX002, for the treatment of relapsed or refractory AML and high-risk MDS. The ARC-T-cells and the SparX proteins comprising ACLX-001 and ACLX-002 are entirely novel and neither had been previously tested in humans prior to the initiation of our Phase 1 trial of ACLX-001. All SparX proteins are comprised of one or more antigen-specific binding domains fused to a protein that we refer to as the TAG. The TAG is a novel protein sequence derived from the 26kDA C-terminal fragment of human alpha fetoprotein ("hAFP") and also had never been previously tested in humans prior to the initiation of our Phase 1 trial of ACLX-001. The ARC-T-cells are designed to

have a binding domain that recognizes the TAG, which we refer to as anti-TAG. The anti-TAG had also never been previously tested in humans prior to the initiation of our Phase 1 trial of ACLX-001. There can be no assurance that the ARC-T-cells, the SparX proteins, the TAG, anti-TAG and other parts of ACLX-001 and ACLX-002 will not trigger an adverse response, cause unintended off-target recognition, limit the expected activity of the product candidates or result in other negative outcomes.

Additionally, because all product candidates in our ARC-SparX platform use the ARC-T-cells, a failure with ACLX-001 or ACLX-002 will increase the actual or perceived likelihood that our other product candidates in the ARC-SparX platform will experience similar failures.

Our Phase 1 trials of ACLX-001 and ACLX-002 are intended to serve as clinical validation of our ARC-SparX platform as we seek to understand the pharmacokinetics, safety profile, and dosing strategy for future clinical development. Upon completion of the Phase 1 trials, we will leverage knowledge gained from these trials to further advance our AML/MDS programs utilizing ARC-SparX for a broader pipeline in this disease area. If we do not successfully complete the Phase 1 trials for ACLX-001 and ACLX-002 in a timely manner or fail to achieve favorable results from the trial, we may experience significant delays or other issues in advancing our other ARC-SparX product candidates, and our other discovery projects in AML/MDS and other tumor settings.

Clinical development is a lengthy, expensive and uncertain process. Our clinical trials may fail to demonstrate adequate safety and/or efficacy of any of our product candidates, which would prevent or delay regulatory approval and commercialization and potentially impact the development of our other product candidates.

Before obtaining regulatory approvals for the commercial sale of our product candidates, including CART- ddBCMA, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates have adequate safety and efficacy profiles, and the manufactured drug product has quality attributes that are appropriate for use in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during clinical development, and, because our product candidates are in an early stage of development, there is a high risk of failure and we may never succeed in developing marketable products.

The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials, particularly because early trials have smaller numbers of subjects tested. In addition, it is not uncommon for product candidates to exhibit unforeseen safety or efficacy issues, such as immunogenicity, when tested in humans despite promising results in preclinical animal models.

Any clinical trials that we may conduct may not demonstrate the safety and efficacy profiles necessary to obtain regulatory approval to market our product candidates. As we continue developing our product candidates, additional serious adverse events, undesirable side effects, or unexpected characteristics may cause us to make further protocol amendments or change our clinical trial design. In some cases, we may be required to limit their development to more narrow uses or subpopulations in which the risk-benefit ratio is more acceptable, or abandon these product candidates or their development altogether.

Treatment with our product candidates may cause side effects or adverse events that are unrelated to our product candidate but may still impact the success of our clinical trials. The inclusion of patients with significant co-morbidities in our clinical trials may result in deaths or other adverse medical events due to an underlying condition or other therapies or medications that such patients may be using. As described above, any of these events could lead to another clinical hold, and/or prevent us from obtaining regulatory approval or achieving or maintaining market acceptance and impair our ability to commercialize our product candidates. Because the product candidates in our platforms share similar components, such as the D-Domain, a failure of one of our clinical trials may also increase the actual or perceived likelihood that our other product candidates will experience similar failures.

In June 2023, the FDA issued a partial clinical hold on CART-ddBCMA. Although the FDA has lifted its partial clinical hold, there is no assurance that the FDA will not issue another clinical hold in the future. Addressing a clinical hold takes considerable time and expense to address and there can be no assurance that the FDA will remove a clinical hold in a timely manner, or at all, in which case our business and prospects for development and approval of CART-ddBCMA would be materially harmed.

In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to a variety of factors, including, but not limited to, changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. If our ongoing or future clinical trials are inconclusive with respect to the safety and efficacy of our product candidates, or if we encounter safety concerns 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 restrictions on use or distribution 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 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 ("REMS");

•Be subject to the addition of labeling statements, such as warnings or contraindications;

•Be sued; and/or

•Experience damage to our reputation.

In addition, even if the trials are successfully completed, clinical data are often susceptible to varying interpretations and analyses, and we cannot guarantee that the FDA or foreign health authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. We cannot guarantee that the FDA or foreign health authorities will view any of our product candidates as having adequate safety and efficacy profiles even if favorable results are observed in these clinical trials, and we may receive unexpected or unfavorable feedback from the FDA or foreign health authorities regarding satisfaction of safety, purity and potency (including clinical efficacy), amongst other factors. To the extent that the results of the trials are not satisfactory to the FDA or foreign health authorities for support of a marketing application, approval of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

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. Events that may prevent successful or timely completion of clinical development include:

•Delays associated with the COVID-19 global pandemic or its lasting effects on the drug development industry, as further described under Risks Related to Our Business;

•Delays in reaching a consensus with regulatory agencies on trial design;

•Delays in reaching agreement on acceptable terms with prospective CROs, and clinical trial sites and obtaining required institutional review board ("IRB"), approval at each clinical trial site;

•Delays in recruiting and enrolling suitable patients to participate in our clinical trials;

•Failure to collect sufficiently viable white blood cells from patients, adequately expand or successfully transduce sufficient number of patient T-cells for infusion or otherwise manufacture product candidates, or infuse patients in a timely manner with product candidate;

•Failure by our CROs, other third parties or us to adhere the trial protocol or the FDA's good clinical practices ("GCPs") or applicable regulatory guidelines in other countries;

•Third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or foreign health authorities for violations of applicable regulatory requirements;

•Delays in the testing, validation, manufacturing and delivery of our product candidates to the clinical trial sites, including due to a facility manufacturing any of our product candidates or any of their components being ordered by the FDA or foreign health authorities to temporarily or permanently shut down due to violations of current good manufacturing practices ("cGMPs") regulations or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;

•Delays in the technology transfer and scale up of our manufacturing process to support late-stage clinical trials;

•Delays in having patients complete their participation in a trial or return for post-treatment follow-up visits;

•Clinical trial sites or patients dropping out of a trial or experiencing changing health or other conditions that require removing them from the trial;

•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 IRBs or Data Safety Monitoring Boards ("DSMBs") or internal clinical holds and/or clinical holds from or by regulatory authorities;

•Lack of adequate funding to continue operations; or

•Changes in regulatory requirements and guidance that require amending or submitting new clinical protocols and/or amendments to INDs.

In June 2023, the FDA issued a partial clinical hold on our IND for CART-ddBCMA following a recent patient death, which involved one clinical trial site treating a patient who was not eligible for CART-ddBCMA infusion and subsequently managing the patient in a manner conflicting with our trial protocol. Although we have aligned with the FDA on modifications to the trial protocol, such amendments may not be sufficient to mitigate future adverse events. Additionally, while we have retrained our clinical trial sites in iMMagine-1 to enhance protocol adherence, there is no assurance that a site or another third party will not deviate from the trial protocol again. Although we announced that the FDA lifted its partial clinical hold on August 14, 2023, there is no assurance that the FDA or DSMB will not issue another clinical hold in the future.

Any inability to successfully complete our clinical trials 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. In addition, if we make material manufacturing changes to our product candidates or change manufacturers, we may need to conduct additional bridging or comparability studies. 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.

If we encounter delays or difficulties enrolling patients in our clinical trials and/or retention of patients in clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until completion of treatment and adequate follow-up. The enrollment of patients depends on many factors, including:

•Inability to enroll, or delay in enrollment of, patients due to outbreaks and public health crises, such as the COVID-19 global pandemic, as further described under Risks Related to Our Business;

•The patient eligibility criteria defined in the protocol;

•The perceived risks and benefits of the product candidate being studied;

•The size of the patient population required for analysis of the trial's primary endpoints;

•The proximity of patients to trial sites;

•The design of the trial;

•The availability of manufacturing slots;

•Our ability to recruit clinical trial investigators with the appropriate competencies and experience;

•Our ability to obtain and maintain patient consent;

•Reporting of the preliminary results of any of our clinical trials; and

•The risk that patients enrolled in clinical trials will drop out of the trials before completion of treatment and adequate follow-up.

In June 2023, the FDA issued a partial clinical hold on CART-ddBCMA. Although we announced that the FDA lifted its partial clinical hold on August 14, 2023, there is no assurance that the FDA or DSMB will not issue another clinical hold in the future, which could further delay enrollment.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigation sites is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our ongoing and planned clinical trials, which could prevent completion or commencement of these trials and adversely affect our ability to advance the development of our product candidates.

Further, conducting clinical trials in foreign countries, as we may do for our product candidates, presents additional risks that may delay completion of our clinical trials. These risks include 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, and acts of war (including ongoing geopolitical tensions related to Russia's actions in Ukraine, resulting sanctions imposed by the United States and other countries, and retaliatory actions taken by Russia in response to such sanctions), relevant to such foreign countries.

Interim, preliminary or topline data from our clinical trials that we announce or publish from time to time 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 publish interim, preliminary or topline data from clinical trials. For example, the data as of the October 31, 2022 data cutoff date for the 38 patients from our Phase 1 clinical trial for CART-ddBCMA for the treatment of rrMM is preliminary data. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary or topline data previously published. As a result, interim, preliminary and topline data should be viewed with caution until the final data are available. Adverse differences between interim, preliminary or topline data and final data could significantly harm our reputation and business prospects.

Moreover, preliminary, interim and topline data are subject to the risk that one or more of the clinical outcomes may materially change as more patient data become available when patients mature on trial, patient enrollment continues or as other ongoing or future clinical trials with a product candidate further develop. Past results of clinical trials may not be predictive of future results.

In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically more extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. Similarly, even if we are able to complete our planned and ongoing preclinical studies and clinical trials of our product candidates according to our current development timeline, the positive results from such preclinical studies and clinical trials of our product candidates may not be replicated in subsequent preclinical studies or clinical trial results.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical and other nonclinical findings made while clinical trials were underway or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. Moreover, preclinical, nonclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA or other regulatory approval.

Our product candidates and the method of treatment may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, require expansion of the trial size, limit their commercial potential, or result in significant negative consequences.

Our product candidates involve genetically modified T cell-based immunotherapies. A number of genetically modified cell therapies, such as CAR-based products, have potentially severe side effects, including cytokine release syndrome, neurologic toxicities, Parkinsonism and Guillain-Barré syndrome, hemophagocytic lymphohistiocytosis, macrophage activation syndrome, and prolonged and/or recurrent cytopenias, that can escalate and require intensive medical intervention and result in injury or death to the patients. Additionally, the administration of CAR-based products for cancer indications involves lymphodepletion and often bridging therapies, which are also associated with adverse events.

There is no guarantee that our product candidates will not have side effects similar to those seen in other genetically modified cell therapies or that we will be able to prevent side effects from escalating to an unsafe level for our patients. Additionally, our initial product candidates are directed at treating patients with rrMM and AML/MDS. These patients are often elderly and/or have significant co-morbidities, and we expect they will receive our product candidate as a last line of therapy after most other therapies have failed, and these patients may be particularly susceptible to safety and toxicity risks. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from T cell therapy may be complicated and difficult to manage, which could result in patient death or other significant issues. Additionally, 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.

In June 2023, the FDA issued a partial clinical hold on our IND for CART-ddBCMA. Although we have aligned with the FDA on modifications to the iMMagine-1 trial protocol, such amendments may not be sufficient to mitigate future adverse events. Additionally, while we have retrained our clinical trial sites in iMMagine-1 to enhance protocol adherence, there is no assurance that a site or another third party will not deviate from the trial protocol again. Although we announced that the FDA lifted its partial clinical hold on August 14, 2023, there is no assurance that the FDA or DSMB will not issue another clinical hold in the future resulting in the suspension or halting of the study.

We have designed a new binding domain that we believe should have low immunogenicity because we also removed potentially immunogenic sequences from their binding domains, which we refer to as “deimmunization.” However, it has never been tested in humans outside of our current clinical trials and we cannot guarantee that there will not be any unexpected side effects from this binding domain or the SparX proteins that we plan to test as part of our product candidates. Although we have completed multiple preclinical studies designed to screen for toxicity caused by unintended off-target recognition *in vivo* by our novel binding domains, our product candidates may still cause unintended off-target recognition in patients. Additionally, our genetically modified T-cells, the ddCARs and the ARC-T-cells, may still bind targets other than the target antigens or the TAG on our SparX proteins, respectively. If significant unexpected binding or off-target binding occurs in normal tissue, our product candidates may target and kill the normal tissue in a patient, leading to serious and potentially fatal adverse events, undesirable side effects, toxicities or other unexpected characteristics. Detection of any significant unexpected or off-target binding may halt or delay any ongoing clinical trials for our product candidates and prevent or delay regulatory approval. While we have developed a preclinical screening process to identify cross-reactivity of our product candidates, we cannot be certain that this process will identify all potential off-target tissue that our product candidates may interact with. Any unexpected or off-target binding that impacts patient safety could materially impact our ability to advance our product candidates into clinical trials and ability to proceed to marketing approval and commercialization.

If additional serious adverse events or undesirable side effects arise, we could be required to suspend, delay, or halt our clinical trials and regulatory authorities could deny approval or require us to limit development of that product candidate to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Undesirable side effects could also result in an expansion in the size of our clinical trials, increasing the expected costs and timeline of our clinical trials. Side effects that are observed during the trial, whether treatment related or not, could also affect patient recruitment for future trials or the ability of enrolled patients to complete the trial or result in potential product liability claims.

Further, if additional serious adverse events or undesirable side effects are identified during development or after approval and are determined to be attributed to any of our product candidates, we may be required to develop 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.

Any of these occurrences may harm our business, financial condition and prospects significantly.

Development of product candidates in combination with other therapies could expose us to additional risks.

Development of any of our product candidates in combination with one or more other therapies that have either been approved or not yet been approved for marketing by the FDA or comparable foreign regulatory authorities could expose us to additional risks, as combination therapies may increase the rate of serious or unexpected adverse events, which could result in a clinical hold as well as pre-approval and post-approval restrictions by the FDA or other regulatory authorities on the proposed combination therapy, including narrowing of the indication, warnings, additional safety data collection and monitoring procedures, and REMS, even if the cause of such serious or unexpected adverse events is not directly attributed to our product candidate. CAR-T therapies for cancer indications, including CART-ddBCMA, are administered following a lymphodepletion regimen and often bridging therapies, these therapies are associated with risks of adverse events. Any of these events or restrictions could have a material adverse effect on our business, delay our regulatory approval, and decrease the market acceptance and profitability of our product candidate if approved for a combination therapy.

We will not be able to market and sell any product candidate in combination with any unapproved therapies that do not ultimately obtain marketing approval. If the FDA or other comparable foreign regulatory authorities do not approve or revoke their approval of other therapies used in combination therapies, or if safety, efficacy, commercial adoption, manufacturing or supply issues arise with such therapies we choose to evaluate in combination with any of our product candidates, we may be unable to obtain approval of or successfully market any one or all of the product candidates we develop.

Even if any of our product candidates were to receive marketing approval or be commercialized for use in combination with other existing approved therapies, we would continue to be subject to the risks that the FDA or other comparable foreign regulatory authorities could revoke approval of the other therapy used in combination with any of our product candidates, or safety, efficacy, manufacturing or supply issues could arise with these existing therapies. In addition, it is possible that existing therapies with which our product candidates are approved for use could themselves fall out of favor or be relegated to later lines of treatment. This could result in the need to identify other combination therapies for our product candidates or our own products being removed from the market or being less successful commercially. Additionally, if the third-party providers of therapies or therapies in development used in combination with our product candidates are unable to produce sufficient quantities for clinical trials or for commercialization of our product candidates, or if the cost of combination therapies is prohibitive, 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.

Manufacturing genetically engineered products is complex and subject to both human and systemic risks. We or our third-party manufacturers may encounter difficulties in production and sourcing and may be subject to variations and supply constraints of key components. 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.

The manufacture of biological drug products, such as ddCARs and ARC-SparX, the components thereof, and the viral vectors used to manufacture these product candidates and components, is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of biologic products often encounter difficulties in production and sourcing, particularly in scaling up or out, validating the production process and assuring high reliability of the manufacturing processes (including the absence of contamination), in light of variations and supply constraints of key components. These problems include logistics and shipping, difficulties with production costs and yields, quality control, including consistency, stability, purity and efficacy of the product, product testing, operator error and availability of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if contaminants are discovered in our supply of our product candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any stability, purity, and efficacy failures, deficiencies, or other issues relating to the manufacture of our product candidates will not occur in the future.

Additionally, our product candidates are derived from cells collected from our patients and such cells may vary in type and quality as the patients may vary in age, stage of disease, and history of treatment among many other factors. We have strict specifications for the patient cell material and the product candidates we manufacture, including certain specifications that are reviewed and approved by regulatory authorities. The patient cell material variability may exceed our manufacturing process capability or deviate from the specified ranges, and result in failure in production of the patient therapy, lower quality batches, or even require adjustments to the specifications approved by authorities. The patient cell material may also be variable in factors that we currently may not be detecting with the analytical methods used or may not know how to measure and we may discover failures with the material after production. We may not be able to deliver the quality and consistency of our cell therapy products that we need or may need to re-collect cell material which can increase costs and/or cause delay, adversely impact patient outcomes and otherwise harm our clinical trials, reputation, business and prospects.

We may fail to manage the logistics of collecting and shipping patient material to the manufacturing site and shipping the product candidate back to the relevant parties and experience delays or shortages of certain clinical or commercial grade supplies and components. Logistical and shipment delays and problems caused by us, our vendors or other factors not in our control, including the pandemic, geopolitical tensions related to Russia's actions in Ukraine, the resulting sanctions imposed by the United States and other countries, and retaliatory actions taken by Russia in response to such sanctions, business interruptions, global supply chain issues, and weather, could prevent or delay the delivery of product candidates to patients. Additionally, we have to maintain a complex chain of identity and chain of custody with respect to patient material as it moves to the manufacturing facility, through the manufacturing processes and back to the patient. Failure to maintain chain of identity and chain of custody could result in patient death, loss of product or regulatory action.

Material modifications in the methods of product candidate manufacturing may result in additional costs or delay.

As product candidates progress from preclinical studies to late-stage clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, materials and processes, are altered along the way in an effort to optimize yield, manufacturing batch size, minimize costs and achieve consistent purity, identity, potency,

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 could affect planned or other clinical trials conducted with product candidates produced using the modified manufacturing methods, materials, and processes. This could delay completion of clinical trials and could require non-clinical or clinical bridging and comparability studies, which could increase costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates, if approved.

If we or our third-party manufacturers or collaborators use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by our third-party manufacturers. We currently outsource all manufacturing to third parties, but we and our manufacturers are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not currently have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

The process for treating cancer patients using T cell therapy is subject to human and systemic risks.

The "vein-to-vein" cycle for treating cancer patients using T cell therapy typically takes approximately four to six weeks and involves a large number of steps and human participants. First, the patient's lymphocytes are isolated by apheresis at the clinical site and shipped to the manufacturing site. Under cGMP conditions at the manufacturing site, the patient's lymphocytes are washed, and then enriched for CD3-positive T-cells using specialized reagents. After overnight culture and T cell activation, the T-cells are transduced using lentiviral vector transduction technology to introduce the CAR and ARC genetic construct into the enriched T cell population. At the completion of T cell transduction, the T-cells are expanded for several days, harvested, formulated into the final drug product and then cryopreserved for delivery to patients. In the United States, samples of the final product are subjected to several release tests which must fulfill specified criteria for the drug product to be released for infusion. These include sterility, identity, purity, potency and other tests. We are subject to stringent regulatory and quality standards in the course of a T cell therapy treatment process, and we cannot assure you that our quality control and assurance efforts will be successful or that the risk of human or systemic errors in these processes can be eliminated.

Prior treatments can alter the cancer and negatively impact chances for achieving clinical activity with our product candidates.

Patients with hematological cancers typically receive highly toxic chemotherapy as their initial treatments that can impact the viability of the T-cells collected from the patient and may contribute to highly variable responses to CAR-T cell therapies. Patients could also have received prior therapies that target the same target antigen on the cancer cells as our intended product candidate and thereby these patients may have cancer cells with low or no expression of the target antigen. As a result, our product candidates may not recognize the cancer cell and may fail to achieve clinical activity.

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

We expect to submit additional INDs for our current and future product candidates. However, our timing for submitting these INDs is dependent on the results of further research. Additionally, we cannot be sure that submission of an IND will result in the FDA allowing further clinical trials to begin, or that, once clinical trials have begun, issues will not arise that suspend or terminate such clinical trials. Additionally, even if the FDA agrees with the design and implementation of the clinical trials set forth in an IND, we cannot guarantee that the FDA will not change its requirements in the future. These risks also apply to other clinical trials we may seek to commence under other INDs or amendments to existing INDs.

The market opportunities for certain of our product candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small, and our projections regarding the size of the addressable market may be incorrect.

We are initially developing CART-ddBCMA as a last line therapy for patients with rrMM with plans to pursue label expansion into earlier lines of therapy. However, there is no guarantee that it, or any of our product candidates, even if approved, would be approved for earlier lines of therapy and any approved products may end up having a smaller market opportunity than we anticipated. Additionally, our projections of both the number of people who have the cancers we are targeting, as well as the size of the subset

patient population who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these cancers. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. As a result, the number of patients may turn out to be fewer than expected.

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 operational 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 intend to utilize with our clinical development strategy. 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. As an example, although we believe that targeting BCMA initially before targeting other antigens will help us validate our platforms more easily, the risks associated with MM patients and the competition in cell therapies targeting BCMA, among others, could outweigh the benefits. 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 face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biopharmaceutical industry is characterized by intense competition and rapid innovation. Our competitors may be able to develop other products or drugs that are able to achieve similar or better results or make it difficult for us to develop our product candidates on a timely basis by limiting our access to patients, clinical trial sites, manufacturers and other resources. Our competitors include large and specialty pharmaceutical companies and biotechnology companies, academic research institutions and governmental agencies, and public and private research institutions. We believe the key competitive factors that will affect the development and commercial success of our product candidates are safety, efficacy, ensuring consistent quality and purity of the product candidates, delivery, price and the availability of reimbursement from government and other third-party payors.

We anticipate substantial direct competition from other organizations developing advanced CAR-T or other types of genetically modified cell therapies due to their promising clinical therapeutic effect in clinical trials, including 2seventy, Abbvie, Allogene, Amgen, Autolus, Bristol-Myers Squibb, Caribou Biosciences, CARsgen, Cartesian, Cellectis, Cellular Biomedicine Group, Celyad, Crispr, Gilead, Gracell, GSK, Innovent, Johnson & Johnson, Legend, Nanjing IASO Biotherapeutics Ltd., Novartis, Pfizer, Poseida Therapeutics, Precision BioSciences, Pregene, Regeneron, and Roche. In addition, we expect to also compete with companies developing:

- T-cells with CARs that are reactive to tumor associated antigens;
- T-cells with T-cell receptors (“TCRs”) that are reactive to tumor associated antigens;
- T-cells with adapter platforms;
- Bispecifics that bring T-cells and diseased cells into close proximity with each other;
- Other immune cells that can be targeted using antibodies;
- Natural killer (“NK”)-based cell therapies;
- In vivo CAR-T therapeutics; and
- Allogeneic cell therapies.

Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff, greater access to clinical sites and patients, experienced regulatory, marketing and manufacturing teams and well-established sales forces. In addition, many of these competitors are active in seeking patent protection and licensing arrangements in anticipation of collecting royalties for use of technology that they have developed. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in

developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products.

Even if we obtain regulatory approval of our product candidates, the availability and price of our competitors' products could limit the demand and the price we are able to charge for our product candidates. We may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances.

Risks Related to Our Business

Unstable market and economic conditions, including adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non-performance by financial institutions or transactional counterparties, may have serious adverse consequences on our business, financial condition and stock price.

As widely reported, global credit and financial markets have experienced volatility and disruptions recently including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability, and increased inflationary risk. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including Russia's actions in Ukraine, terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the one in Ukraine, may also adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. 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 may 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, or do not improve, it may make any necessary equity or debt 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 these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

In addition, actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank (SVB) was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or the FDIC, as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership.

Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial institutions with which we have arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all.

As of September 30, 2023, we had cash, cash equivalents and marketable securities of $439.7 million. While we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents and marketable securities since September 30, 2023, no assurance can be given that further deterioration of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents and marketable securities or our ability to meet our financing objectives. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

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 an inability to find suitable replacements could result in delays in product development and harm our business.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided equity awards in the form of stock options and restricted stock units that vest over time. The value to employees of equity awards 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 or service with us on short notice. Although we have employment agreements with 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. 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 in an extremely competitive market for employees and other service providers.

We expect to grow the size of our organization, and we may experience difficulties in managing this growth.

As our development and commercialization plans and strategies develop, and as we continue our transition into operating as a public company, we expect to need additional research, development, clinical, quality assurance, statistical analysis, managerial, operational, sales, marketing, financial and other personnel, as well as additional facilities to expand our operations, including for in-house manufacturing capabilities. Future growth would impose significant added responsibilities on members of management, including:

•Identifying, recruiting, integrating, retaining and motivating additional employees and other service providers;

•Managing our internal development efforts effectively, including the clinical and FDA review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and

•Improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may have to divert 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, or spend additional resources to add those capabilities or outsource them.

We currently rely and for the foreseeable future will continue to rely on certain independent organizations, advisors and/or consultants to provide certain services, including regulatory advice, clinical trial support and drug product manufacturing. There can be no assurance that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed and at a reasonable cost, or that we can find qualified replacements if the need arises. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent contractors and consultants on economically reasonable terms in a timely manner, or at all.

We do intend to transition some regulatory, clinical trial execution, and manufacturing capabilities in-house, but in order to do so, will need to identify, recruit and build experienced teams and there are no assurances that we will be able to do so.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, or we are not able to effectively build out new facilities to accommodate this expansion, 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.

Our internal computer systems and networks, or those used by our third-party CROs, other contractors, consultants or collaborators, may fail or suffer security breaches or incidents, which could result in a material disruption of the development programs of our product candidates.

Despite the implementation of security measures, our internal computer systems and networks and those of our current and future CROs and other contractors and consultants are vulnerable to damage, breakdown, or interruption from computer viruses, ransomware, or other malware, phishing, social engineering, fraudulent inducement, electronic fraud, wire fraud, human error or

malfeasance, unauthorized access, natural disasters, and telecommunication and electrical failures. For example, our employees have received and likely will continue to receive phishing or “spoofed” emails to induce them to make payments to fraudulent accounts. While we have not experienced any such material system failure or security breach or incident to date, if such an event were to occur impacting ourselves or our current or future CROs or other contractors or consultants, it could result in a material disruption of our development programs and our business operations and could lead to the loss of confidential information, financial assets, trade secrets or other intellectual property, or could lead to unauthorized access to or use, modification, unavailability, disclosure, loss or acquisition of, or the public exposure of, personal information (including sensitive personal information) of our employees, customers and others, or confidential information of ourselves or of third parties that we maintain, any of which could have a material adverse effect on our business, reputation, financial condition and results of operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we currently rely on third parties to manufacture our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business.

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 (including our products/services) or the third-party information technology systems that support us and our services.

Any disruption or security breach or incident could compromise our networks and systems, or those of our current or future CROs or other contractors or consultants, could result in a loss of, or damage to, our data or applications, or unauthorized access to or use, modification, unavailability, disclosure, loss or acquisition of, or the public exposure of, personal information (including sensitive personal information) of our employees, customers and others, or confidential information of ourselves or of third parties that we maintain, and could result in legal claims or proceedings, regulatory investigations or other proceedings, liability under laws that protect the privacy of personal information, mandatory notification and reporting obligations, additional regulatory oversight, significant regulatory penalties and remediation expenses.

In addition, these breaches and incidents and other inappropriate access can be difficult to detect, remediate, and otherwise address, and may remain undetected or not fully addressed for an extended period. Any delay in identifying them and responding to or otherwise remediating them may lead to increased harm of the type described above. We expect to continue to expend significant resources to protect against security breaches and incidents and could be required to expend significant amounts to remediate and otherwise respond to security breaches and incidents, including in connection with making notifications to individuals or other persons or implementing additional security measures. With the increase in personnel working remotely during and after the COVID-19 pandemic, we and our vendors are at increased risk for security breaches and incidents.

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 privacy, data protection, or data security. 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, data protection, or data 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 employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

Our business operations and current and future relationships with investigators, health care professionals, consultants, third-party payors and customers will be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, 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. We are exposed to the risk of employee fraud or other illegal or detrimental activity by our employees, independent contractors, consultants, commercial partners, vendors and agents acting on behalf of us or our affiliates. Misconduct by these parties could include, without limitation, intentional, reckless and/or negligent conduct that fails to: comply with the regulations of the FDA or foreign health authorities; provide true, complete and accurate information to the FDA or foreign health authorities; comply with manufacturing standards we have established; comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or report financial information or data accurately or to disclose unauthorized activities to us; or that negatively reflects on our reputation or business.

We will face increasing regulation as we advance our product candidates through clinical trials and pursue commercialization, if approved.

If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws and regulations will increase significantly, and our costs associated with compliance with such laws and regulations are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. In particular, the

promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. The laws that may affect our ability to operate include, but are not limited to the following:

•The federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs.

•The federal civil and criminal false claims laws, including the civil False Claims Act (“FCA”), that can be enforced by private citizens through civil whistleblower or qui tam actions, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. No specific intent to defraud is required under the civil FCA. The criminal FCA provides for criminal penalties for submitting false claims, including imprisonment and criminal fines.

•The Civil Monetary Penalty Act of 1981 and implementing regulations, which impose penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent, or offered or transferred remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary’s decision to order or receive items or services reimbursable by the government from a particular provider or supplier.

•The federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters.

•HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (“HITECH”), and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization.

•The federal Physician Payment Sunshine Act, created under the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act of 2010, collectively, the Affordable Care Act (“ACA”), and its implementing regulations, which require applicable manufacturers of covered drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services (“CMS”) of the U.S. Department of Health and Human Services (“HHS”) information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), non-physician healthcare professionals (such as physician assistants and nurse practitioners, among others) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

•Additional requirements and regulations applicable to the distribution of pharmaceutical products, including extensive record-keeping, licensing, price reporting, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products. Pricing and rebate programs must also comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the ACA. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws.

•Federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Additionally, we are subject to state and foreign equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payor.

Our board of directors has adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations.

Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

We may not realize the benefits of any acquisitions, in-licenses or strategic alliances that we enter into.

In the future, we may seek and form strategic alliances, create joint ventures or collaborations, or enter into acquisitions or additional licensing arrangements with third parties that we believe will complement or augment our existing technologies and product candidates, including artificial intelligence, machine learning and other technology-based platforms that may supplement our discovery efforts.

These transactions can entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention in order to manage a collaboration or develop acquired products, product candidates or technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business. As a result, if we enter into acquisition or in-license agreements or strategic 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, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction or such other benefits that led us to enter into the arrangement.

We may become exposed to costly and damaging product liability claims, either when testing our product candidates in the clinic or at the commercial stage, and our product liability insurance may not cover all damages from such claims.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- Decreased demand for our product candidates or products that we may develop;
- Impairment of our business reputation;
- Withdrawal of clinical trial participants;
- Initiation of investigations by regulators;
- Costs to defend the related litigation;
- A diversion of management's time and our resources;

•Substantial monetary awards to trial participants or patients;

•Product recalls, withdrawals or labeling, marketing or promotional restrictions;

•Loss of revenue;

•Exhaustion of any available insurance and our capital resources;

•The inability to commercialize any product candidate; and

•A decline in our share price.

Failure to obtain or retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with corporate collaborators. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

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 or course of treatment. 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 product candidates, 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 product candidates, 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.

Although we maintain product liability insurance coverage, such insurance may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage each time we commence a clinical trial and if we successfully commercialize any product candidate. As the expense of insurance coverage is increasing, we may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

Changes in tax laws or in their implementation or interpretation may adversely affect our business and financial condition.

Recent changes in tax law may adversely affect our business or financial condition. For example, in 2021, there were numerous changes proposed to U.S. federal income tax law, including an increase to the U.S. corporate tax rate, international business operations reform and the imposition of a global minimum tax. If these or similar changes are enacted, our effective tax rate may be adversely impacted in future years. Additionally, many countries, including the United States, and organizations such as the Organization for Economic Cooperation and Development are also actively considering changes to existing tax laws or have proposed or enacted new laws that could increase our tax obligations in countries where we do business or cause us to change the way we operate our business. Any of these developments or changes in federal, state, or international tax laws or tax rulings could adversely affect our effective tax rate and our operating results. We urge prospective investors in our common stock to consult with their legal and tax advisors with respect to any recently enacted tax legislation, or proposed changes in law, and the potential tax consequences of investing in or holding our common stock. On January 1, 2022, a provision of the legislation commonly known as the Tax Cuts and Jobs Act of 2017 (the “2017 Tax Act”) went into effect, eliminating the option to deduct domestic research and development costs in the year incurred and instead requiring taxpayers to amortize such costs over five years. We are currently evaluating the potential impact of this provision.

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business and financial condition.

Legislation enacted on December 22, 2017, known as the Tax Cuts & Jobs Act (“TCJA”), significantly revises the Internal Revenue Code of 1986, as amended. The TCJA, as modified by tax provisions in the CARES Act, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the deduction for net operating losses (“NOLs”) to 80% of current year taxable income and elimination of NOL carrybacks, in each case for tax years beginning after 2020, one-time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, creation of a base erosion and

anti-abuse tax and modification or repeal of many business deductions and credits. Several aspects of the TCJA remain unclear and may not be clarified for some time. Future guidance from the Internal Revenue Service and other tax authorities with respect to the TCJA may affect us, and certain aspects of the TCJA could be repealed or modified in future legislation, as they were by the CARES Act. Notwithstanding the reduction in the corporate income tax rate, it is possible that the TCJA, the CARES Act, or regulations or interpretations under them, or any other future changes in tax laws, could adversely affect our business and financial condition, and such effect could be material.

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

Under Sections 382 and 383 of the Internal Revenue Code, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change (by value) by 5-percent shareholders in its equity ownership over a three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes (including tax credit carryforwards) to offset its post-change taxable income may be limited. As a result of our most recent private placements, our initial public offering, and other transactions that have occurred over the past three years, we experienced such an "ownership change." We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. Under the TCJA, NOLs arising in tax years beginning after December 31, 2017 can only offset 80% of annual taxable income for tax years beginning after December 31, 2020, but can be carried forward indefinitely. Our use of net operating losses generated years beginning before January 1, 2018 will not be subject to the annual taxable income limitation and will continue to have a 20-year carryforward period. In addition, we will be unable to use our net operating loss carryforwards and tax credit carryforwards if we do not generate taxable income sufficient to offset our available net operating loss carryforwards and tax credit carryforwards prior to their expiration.

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. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire, except as described below.

Under the TCJA, federal NOLs incurred in taxable years beginning after 2017 and in future years may be carried forward indefinitely, but the deductibility of such federal NOLs for taxable years beginning after 2020 is limited. In addition, under Section 382 of the Code, our ability to utilize NOL carryforwards or other tax attributes, such as research tax credits, in any taxable year may be limited if we experience an "ownership change." Generally, a Section 382 ownership change occurs if there is a cumulative increase of more than 50 percentage points in the stock ownership of one or more stockholders or groups of stockholders who owns at least 5% of a corporation's stock within a specified testing period. Similar rules may apply under state tax laws. We performed an ownership change study of as December 31, 2022 and we determined that certain NOLs and research and developments tax credits for both federal and state purposes were severely limited and therefore we removed a significant amount of NOLs and research and development tax credits from our deferred tax assets. In the future we may experience additional ownership changes from future offerings or other changes in the ownership of our stock that could further limit the amount of NOLs or other tax attributes presented in our financial statements. In addition, state suspensions of the ability to use NOLs, and research credits such as California's June 2020 temporary suspension and limitation on use of such attributes, may limit our ability to use our NOLs and research credits to offset state taxable income and taxes.

Our business may be significantly adversely affected if events out of our control, such as the COVID-19 pandemic, disrupt our business or that of our third-party providers.

Our business could be significantly adversely affected by business disruptions to us or our third-party providers that could seriously harm our potential future revenue and financial condition and increase our costs and expenses. Our operations, and those of our CROs, CMOs, and other contractors, consultants, and third parties could be subject to global pandemics (such as the COVID-19 pandemic), other geopolitical uncertainty and instability (including Russia's actions in Ukraine), earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce and process our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

While the extent of the impact of the recent COVID-19 pandemic on our business and financial results to date has been limited, the lasting effects of the pandemic on the drug development industry remains uncertain. A prolonged public health crisis such as the COVID-19 pandemic could have a material negative impact on our business, financial condition and operating results. We have experienced and may in the future experience disruptions from COVID-19 to our business in a number of ways, including:

- Delays in supply chain and manufacturing, including the closure of apheresis collection centers, suspension of cell transport, limitations on transfer of technology, shutdown of manufacturing facilities and delays in delivery of supplies and reagents;

•Delays in discovery and preclinical efforts;

•Changes to procedures or shut down, or reduction in capacity, of clinical trial sites due to limited availability of clinical trial staff, reduced number of inpatient intensive care unit beds for patients receiving cell therapies, diversion of healthcare resources away from clinical trials and other business considerations;

•Limited patient access, enrollment and participation due to travel restrictions and safety concerns, as well as housing and travel difficulties for out of town patients and relatives; and

•Changes in regulatory and other requirements for conducting preclinical studies and clinical trials during the pandemic.

We may be required to develop and implement additional clinical trial policies and procedures designed to help protect subjects from infectious diseases such as the COVID-19 virus. On May 11, 2023, the federal government ended the COVID-19 public health emergency, which ended a number of temporary changes made to federally funded programs, while some continue to be in effect. The full impact of this termination of the national emergency and the wind-down of the public health emergency on FDA and other regulatory policies and operations are unclear.

Risks Related to Reliance on Third Parties

We rely, and will continue to rely, on third parties to conduct our clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.

We do not have the ability to conduct all aspects of our preclinical testing or clinical trials ourselves. We depend and will depend upon independent investigators and collaborators, such as medical institutions, CROs, CMOs and strategic partners to conduct our preclinical studies and clinical trials under agreements with us. We expect to negotiate budgets and contracts with CROs, trial sites and CMOs, which may result in delays to our development timelines and increased costs. We will rely heavily on these third parties over the course of our clinical trials, and we control only certain aspects of their activities. As a result, we have less direct control over the conduct, timing and completion of these clinical trials and the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCPs, which are regulations and guidelines enforced by the FDA or foreign health authorities for product candidates in clinical development.

Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or foreign health authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP regulations. In addition, our clinical trials must be conducted with biologic product produced under cGMP regulations and may require a significant number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our clinical trials are not and will not be our employees and, except for remedies available to us pursuant to our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to such trials. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative providers or do so on commercially reasonable terms. Switching or adding third parties to conduct our clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines.

We rely and expect to continue to rely on third parties to manufacture our clinical product supplies and clinical candidates, and we may rely on third parties for at least a portion of the manufacturing process of our product candidates, if approved. Our business could be harmed if those third parties fail to provide us with sufficient quantities of product supplies or product candidates or fail to do so at acceptable quality levels or prices.

We do not currently own any facility that may be used as a clinical-scale manufacturing and processing facility, and we rely on outside vendors and collaborators to manufacture supplies and process our product candidates. For certain of our components or product candidates, we rely on single suppliers or manufacturers to supply or manufacture, but we plan to expand the number of suppliers and manufacturers as we advance our product candidates through clinical development. Our product candidates are not yet manufactured or processed on a commercial scale and we may remain unable to do so for any of our product candidates. Although in the future we may develop our own manufacturing facilities, we may also continue to use third parties as part of our manufacturing processes and may, in any event, never be successful in developing our own manufacturing facilities. Our anticipated reliance on third-party manufacturers exposes us to the following risks:

•We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA must inspect any manufacturers for current cGMP.

•Non-compliance of our third-party manufacturers with requirements of our marketing application(s). In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, the production of our product candidates.

•Third-party manufacturers may have little or no experience with our product candidates, and therefore may require a significant amount of support from us in order to implement and maintain the infrastructure and processes required to manufacture our product candidates.

•Third-party manufacturers might be unable to timely manufacture our product candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any.

•Third-party manufacturers may not be able to execute our manufacturing procedures and other logistical support requirements appropriately.

•Third-party manufacturers may not perform as agreed, may not devote sufficient resources to our product candidates or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store, and distribute our products, if any.

•Manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.

•We may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing processes for our product candidates.

•Our third-party manufacturers could breach or terminate their agreements with us, and we may be required to pay fees upon suspension or termination of the agreement even if the manufacturers do not deliver adequate supply of the product candidates or their components.

•Raw materials and components used in the manufacturing processes, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to factors beyond our control.

•Our third-party manufacturers may have unacceptable or inconsistent product quality success rates and yields, and we have no direct control over their ability to maintain adequate quality control, quality assurance and qualified personnel.

Each of these risks could delay or prevent the completion of our clinical trials or the approval of any of our product candidates by the FDA, result in higher costs or adversely impact commercialization of our product candidates. In addition, we will rely on third parties to perform certain specification tests on our product candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm and the FDA could place significant restrictions on our company until deficiencies are remedied. Furthermore, our or a third party's failure to execute on our manufacturing requirements, to do so on commercially reasonable terms or to 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.

If any CMO with whom we contract fails to perform its obligations, we may be forced to enter into an agreement with a different CMO, which we may not be able to do on reasonable terms, if at all. In such scenario, our clinical trials supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original CMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CMOs for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new CMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

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.

We have entered into a Collaboration Agreement with Kite, and pursuant to the terms of that agreement, are dependent on Kite for certain development and commercialization activities with respect to certain of our product candidates.

In January 2023, we announced the closing of the Collaboration and License Agreement (Kite Collaboration Agreement) with Kite Pharma, Inc., a Gilead Company (Kite), pursuant to which we agreed to collaborate with Kite to co-develop and co-commercialize CART-ddBCMA and next-generation autologous and non-autologous CAR-T cell therapy products that use the same D-domain BCMA binder used in CART-ddBCMA, in each case for the treatment of multiple myeloma. We also granted Kite an option to include autologous CAR T-cell therapy products that utilize our ARC-SparX platform that are directed to BCMA, such as ACLX-001, as well as ARC-SparX products directed to CS1. Pursuant to the Kite Collaboration Agreement, we and Kite will jointly develop CART-ddBCMA and any next-generation autologous CAR-T cell therapy product for which we may exercise our option to co-promote with Kite (collectively, the Co-Promote Products) in accordance with mutually agreed development plans and development budgets. We will conduct the iMMagine-1 trial for CART-ddBCMA and Kite will conduct all other development of the other Co-Promote Products. Kite will be responsible for commercialization of CART-ddBCMA and such other MM products, outside the United States, to the extent they are approved by the applicable regulatory authorities. We cannot control whether Kite will devote sufficient attention or resources to this collaboration or will proceed in an expeditious manner. Even if the FDA or other regulatory

agencies approve any of the Co-Promote Products, Kite may elect not to proceed with the commercialization of the resulting product in one or more countries.

In the United States, we and Kite will equally share profits and losses from the commercialization of the Co-Promote Products. For Co-Promote Products outside of the United States and for any other products we may license to Kite that are not a Co-Promote Product (Non-Co-Promote Products), we will be eligible for tiered royalties in the low to mid teen percentages. The milestones that trigger a payment or royalties under the Kite Collaboration Agreement may never be reached and failure to do so could harm our business and financial condition.

Kite has customary rights to terminate the Kite Collaboration Agreement, and if Kite elects to exercise these termination rights, it will result in a delay in or could prevent us from developing or commercializing certain product candidates. Further, disputes may arise between us and Kite, which may delay or cause the termination of this collaboration, result in significant litigation, cause Kite to act in a manner that is not in our best interest or cause us to seek another collaborator or proceed with development, commercialization and funding on our own. If we seek a new collaborator but are unable to do so on acceptable terms, or at all, or do not have sufficient funds to conduct the development or commercialization of such development candidates we may have to curtail or abandon that development or commercialization, which could harm our business.

In addition to our collaboration with Kite, we may seek to establish future collaborations, and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

In addition to our collaboration with Kite, we may seek future collaboration arrangements with other parties for the development or commercialization of our product candidates. The success of any collaboration arrangements may depend on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these arrangements. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision making authority.

Collaborations with biopharmaceutical companies and other third parties often are terminated or are allowed to expire by the other party. Any such termination or expiration could adversely affect us financially and could harm our business reputation.

Any future collaborations we might enter into may pose a number of risks, including the following:

•Collaborators may not perform their obligations as expected;

•Collaborators may not pursue development and commercialization of product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding or external factors, such as an acquisition, that divert resources or create competing priorities;

•Collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;

•Collaborators could fail to make timely regulatory submissions for a product candidate;

•Collaborators may not comply with all applicable regulatory requirements or may fail to report safety data in accordance with all applicable regulatory requirements, which could subject them or us to regulatory enforcement actions;

•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;

•Product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;

•A collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product candidate or product;

•Disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time consuming and expensive;

•Collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation; and

•Collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability.

In addition, if we establish one or more collaborations, all of the risks relating to product development, regulatory approval and commercialization described in this Quarterly Report on Form 10-Q would also apply to the activities of any such future collaborators.

If any collaborations we might enter into in the future do not result in the successful development and commercialization of products or if one of our future collaborators subsequently terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under such potential future collaboration. If we do not receive the funding we expect under the agreements, our development of our product candidates could be delayed and we may need additional resources to develop our product candidates and our platforms.

Additionally, if any future collaborator of ours is involved in a business combination, the collaborator might de-emphasize or terminate development or commercialization of any product candidate licensed to it by us. If one of our future collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our reputation in the business and financial communities could be adversely affected.

We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for any collaboration will depend upon, among other things, our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms, or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our platforms and our business may be materially and adversely affected.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for our platforms and our 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 platforms, product candidates and research programs. 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 that protect our product candidates or their intended uses or that 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. 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, CROs, CMOs, 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. Defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, etc., although we are unaware of any such defects that we believe are of material import.

If we, or any future licensors or licensees, fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If any future licensors or licensees, are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable. Any of

these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Composition of matter patents for biological and pharmaceutical products such as proprietary binding domains and CAR-based product candidates often provide a strong form of intellectual property protection for these types of products 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 U.S. Patent and Trademark Office ("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 or administrative tribunals in the United States or foreign countries.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and in recent years has been the subject of much litigation, resulting in court decisions, including Supreme Court decisions, that 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, 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.

The patent application process is subject to numerous risks and there can be no assurance that we will be successful in obtaining patents for which we have applied.

Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent is issued for such applications. The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future development partners will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case;

- The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance;

- Patent applications may not result in any patents being issued;

- Patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, narrowed, found to be unenforceable or otherwise may not provide any competitive advantage;

- Our competitors, many of whom have substantially greater resources and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use, and sell our potential product candidates;

•There may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both in the United States and abroad for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and

•Countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates.

Any of the foregoing events 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 our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our market.

We rely upon a combination of patents, confidentiality agreements, trade secret protection and intellectual property and confidentiality agreements to protect the intellectual property related to our technologies. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

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

•If and when patents will issue based on our patent applications;

•The scope of protection of any patent issuing based on our patent applications;

•The degree and range of protection any issued patents will afford us against competitors including whether third parties will find ways to invalidate or otherwise circumvent our patents;

•Whether any of our intellectual property will provide any competitive advantage;

•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 or defend litigation or administrative proceedings to enforce and/or defend our patent rights, which may be costly whether we win or lose; or

•Whether the patent applications that we own or may 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 or administrative tribunals in the United States or foreign countries.

The strength of patents in the biotechnology and cell therapy fields involve complex legal and scientific questions and can be uncertain. The patent applications that we own or may in-license may fail to result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the breadth or strength of protection provided by the patent applications we hold 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. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our product candidates. Furthermore, for U.S. applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third party or instituted by the USPTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. Various post grant review proceedings, such as *inter partes* review and post grant review, are available for any interested third party to challenge the patentability of claims issued in patents to us. While these post grant review proceedings have been used less frequently to invalidate biotech patents, they have been successful regarding other technologies, and these relatively new procedures are still changing, and those changes might affect future results.

In addition to the protection afforded by patents, we seek to rely on trade secret protection, confidentiality agreements, and other agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our product discovery and development processes that involve proprietary know-how, information, or technology that is not covered by patents. Although we require all of our employees to assign their inventions to us, and require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, 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. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition.

Numerous factors may limit any potential competitive advantage provided by our intellectual property rights.

The degree of future protection afforded by our intellectual property rights, whether owned or in-licensed, is uncertain because intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors, or permit us to maintain our competitive advantage. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The following examples are illustrative:

- Pending patent applications that we own or may license may not lead to issued patents;
- Patents, should they issue, that we own or may license, may not provide us with any competitive advantages, or may be challenged and held invalid or unenforceable;
- Others may be able to develop and/or practice technology that is similar to our technology or aspects of our technology but that is not covered by the claims of any patents that we own or may license, should any such patents issue;
- Third parties may compete with us in jurisdictions where we do not pursue and obtain patent protection;
- We (or any licensors) might not have been the first to make the inventions covered by a pending patent application that we own or may license;
- We (or any licensors) might not have been the first to file patent applications covering a particular invention;
- Others may independently develop similar or alternative technologies without infringing our intellectual property rights;
- We may not be able to obtain necessary licenses on reasonable terms or at all;
- Third parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights, or any rights at all, over that intellectual property;

•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 not be able to maintain the confidentiality of our trade secrets or other proprietary information;

•We may not develop or in-license additional proprietary technologies that are patentable; and

•The patents of others may have an adverse effect on our business.

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

Third-party claims of intellectual property infringement may prevent or delay our product discovery and development efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, reexamination, and post grant review proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others.

Third parties may assert that we are employing their proprietary technology without authorization. Generally, conducting clinical trials and other development activities in the United States is not considered an act of infringement. If and when one of our product candidates is approved by the FDA, a third party may then seek to enforce its patent by filing a patent infringement lawsuit against us. While we do not believe that any claims that could otherwise materially adversely affect commercialization of our product candidates, if approved, are valid and enforceable, we may be incorrect in this belief, or we may not be able to prove it in a litigation. In this regard, patents issued in the United States by law enjoy a presumption of validity that can be rebutted only with evidence that is “clear and convincing,” a heightened standard of proof. There may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications, which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Moreover, we may fail to identify relevant patents or incorrectly conclude that a patent is invalid, not enforceable, exhausted, or not infringed by our activities. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing processes of our product candidates, constructs or molecules used in or formed during the manufacturing processes, or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, could involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need or may choose to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly.

We may become involved in lawsuits to protect or enforce our patents, 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. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in

question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful infringement claim against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure.

Post-grant proceedings, including interference proceedings, provoked by third parties or brought by the USPTO may be necessary to determine the validity or priority of inventions with respect to our patents or those of any licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation or post-grant proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with any licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

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.

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

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in 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. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business. Failure by us or any licensor to maintain protection of our patent portfolio 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 to launch their product earlier than might otherwise be the case, and our revenue could be reduced, possibly materially.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court or the USPTO.

If we or a licensing partner initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, inter parties review, post grant review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business.

Changes in U.S. patent law 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 any licensed patents. Patent reform legislation in the United States and other countries, including the Leahy-Smith

America Invents Act (the “Leahy-Smith Act”), signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

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.

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

Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection or licenses but enforcement is not as strong as that 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.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and

proprietary rights generally. Proceedings to enforce our intellectual property and proprietary 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, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or may license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected.

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

Although we are not currently aware of any claims challenging the inventorship of our patents or ownership of our intellectual property, we may in the future 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. We generally enter into confidentiality and intellectual property assignment agreements with our employees, consultants, and contractors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, those agreements may not be honored and may not effectively assign intellectual property rights to us. Moreover, there may be some circumstances, where we are unable to negotiate for such ownership rights. Disputes regarding ownership or inventorship of intellectual property can also arise in other contexts, such as collaborations and sponsored research. If we are subject to a dispute challenging our rights in or to patents or other intellectual property, such a dispute could be expensive and time consuming. If we were unsuccessful, we could lose valuable rights in intellectual property that we regard as our own, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

We may receive confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of these third parties or our employees' former employers or our consultants' or contractors' current or former clients or customers. Although we try to ensure that our employees and consultants do not use 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 his or her 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. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees. If we are not successful, we could lose access or exclusive access to valuable intellectual property.

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 our technology and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. 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. Detecting the disclosure or misappropriation of a trade secret and 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, we would have no right to prevent them, or those to whom they communicate it, 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, our competitive position would be harmed.

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

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

Moreover, any name we may propose to use 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 Government Regulation

We may be unable to obtain regulatory approval for our product candidates. The denial or delay of any such approval would delay commercialization and have a material adverse effect on our potential to generate revenue, our business and our results of operations.

The research, development, testing, manufacturing, labeling, packaging, approval, promotion, advertising, storage, record keeping, marketing, distribution, post-approval monitoring and reporting, and export and import of drug products are subject to extensive regulation by the FDA, and by foreign health authorities in other countries. These regulations differ from country to country. 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 gain approval to market our product candidates, we must provide clinical data that adequately demonstrate the safety and efficacy of the product for the intended indication. We have not yet obtained regulatory approval to market any of our product candidates in the United States or any other country. Our business depends upon obtaining these regulatory approvals. The FDA can delay, limit or deny approval of our product candidates for many reasons, including:

- Our inability to satisfactorily demonstrate that the product candidates have acceptable safety and efficacy profiles for the requested indication;
- The FDA's disagreement with our trial designs or the interpretation of data from preclinical studies or clinical trials;
- The population studied in the clinical trial may not be sufficiently broad or representative to assess safety in the full population for which we seek approval;
- Our inability to demonstrate that clinical or other benefits of our product candidates outweigh any safety or other perceived risks;
- The FDA's determination that additional preclinical or clinical trials are required;
- The FDA's non-approval of the formulation, labeling or the specifications of our product candidates;

•The FDA's failure to accept the manufacturing processes, drug product characteristics or facilities of third-party manufacturers with which we contract; or

•The potential for approval policies or regulations of the FDA to significantly change in a manner rendering our clinical data insufficient for approval.

Even if we eventually complete clinical testing and receive approval of any regulatory filing for our product candidates, the FDA may grant approval contingent on the performance of costly additional post-approval clinical trials. The FDA may also approve our product candidates for a more limited indication or a narrower patient population than we originally requested, and the FDA may not approve the labeling that we believe is necessary or desirable for the successful commercialization of our product candidates. If FDA requires us to narrow our indications to smaller patient subsets, our market opportunities for our product candidates, if approved, and our ability to generate revenues may be materially limited. To the extent we seek regulatory approval in foreign countries, we may face challenges similar to those described above with regulatory authorities in applicable jurisdictions.

Any delay in obtaining, or inability to obtain, applicable regulatory approval for any of our product candidates would delay or prevent commercialization of our product candidates and would materially adversely impact our business, results of operations and prospects.

The FDA regulatory approval process is lengthy, time-consuming and inherently unpredictable, and we may experience significant delays in the clinical development and regulatory approval of our product candidates or be unable to generate product revenue.

We have not previously submitted a BLA to the FDA or similar marketing applications to foreign health authorities. A BLA must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety, purity and efficacy for each desired indication. The BLA must also include significant information regarding the manufacturing controls for the product. The novel nature of our product candidates may introduce uncertain, complex, expensive and lengthy challenges that could impact regulatory approval. Even if we eventually complete clinical testing and receive approval of any regulatory filing for our product candidates, the FDA or foreign health authorities may approve our product candidates for a more limited indication or a narrower patient population than we originally requested.

We may also experience delays in completing planned clinical trials for a variety of reasons, including delays related to:

•The availability of financial resources to commence and complete the planned trials;

•Reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

•Obtaining approval at each clinical trial site by an IRB or ethics committee;

•Recruiting suitable patients to participate in a trial;

•Enrolling and retaining sufficient number of patients to complete a trial, including post-treatment follow-ups;

•Clinical trial sites deviating from trial protocol or dropping out of a trial;

•Adding new clinical trial sites; or

•Manufacturing sufficient quantities of qualified materials under cGMPs and applying them on a subject by subject basis for use in clinical trials.

We could also experience delays in physicians enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments or other clinical trials. Furthermore, a clinical trial may be suspended or terminated by us, the IRBs for the institutions in which such trials are being conducted, the Data Monitoring Committee for such trial, or by the FDA or foreign health authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or foreign health authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue.

In June 2023, the FDA issued a partial clinical hold on CART-ddBCMA. Although we announced that the FDA lifted its partial clinical hold on August 14, 2023, there is no assurance that the FDA will not issue another clinical hold in the future. Addressing a

clinical hold takes considerable time and expense and there can be no assurance that the FDA will remove a clinical hold in a timely manner, or at all, in which case our business and prospects for development and approval of CART-ddBCMA would be materially harmed.

Securing regulatory approval also requires the submission of information about the manufacturing processes and inspection of manufacturing facilities by the relevant regulatory authority. The FDA or foreign health authorities may fail to approve our manufacturing processes or facilities, whether run by us or our CMOs. In addition, if we make manufacturing changes to our product candidates in the future, we may need to conduct additional preclinical and/or clinical studies to bridge our modified product candidates to earlier versions.

Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may ultimately lead to the denial of regulatory approval of our product candidates. Applications for our product candidates could fail to receive regulatory approval for many reasons, including but not limited to the following:

- The FDA or foreign health authorities may disagree with the design, implementation or data analyses of our clinical trials;
- The FDA or foreign health authorities may determine that our product candidate(s) do not have adequate risk-benefit ratio or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use;
- The population studied in the clinical program may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;
- The FDA or foreign health authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- The data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA or other submission or to obtain regulatory approval in the United States or elsewhere;
- The FDA or foreign health authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- The approval policies or regulations of the FDA or foreign health authorities may significantly change in a manner rendering our clinical data insufficient for approval.

We have or may pursue Fast Track, orphan drug, and/or RMAT designations from the FDA for one or more of our product candidates. Even if one or more of our product candidates receive Fast Track, orphan drug, and/or RMAT designations, we may be unable to obtain and maintain the benefits associated with such designations. These designations may not lead to a faster development or regulatory review or approval process, and will not increase the likelihood that such product candidates will receive marketing approval.

To date, CART-ddBCMA has been granted Fast Track, orphan drug, and Regenerative Medicine Advanced Therapy (“RMAT”) designations by the FDA. In the future, we may pursue one or more similar designations for other product candidates, including ACLX-001 and ACLX-002.

Fast Track designation is designed to facilitate the development and expedite the review of therapies for serious conditions with an unmet medical need. Programs with Fast Track designation may benefit from early and frequent communications with the FDA, potential priority review and the ability to submit a rolling application for regulatory review. Fast Track designation applies to both the product candidate and the specific indication for which it is being studied. However, if we do not continue to meet the criteria of the Fast Track designation, or if our clinical trials are delayed, suspended or terminated, or put on clinical hold due to unexpected adverse events or issues with clinical supply, we will not receive the benefits associated with the Fast Track program. Furthermore, Fast Track designation does not change the standards for approval. Fast Track designation alone does not guarantee qualification for the FDA’s priority review procedures. Fast track designation also does not guarantee our product candidate will be approved in a timely manner, if at all. In June 2023, the FDA issued a partial clinical hold on CART-ddBCMA. Although the FDA has lifted its partial clinical hold, there is no assurance the FDA will not issue another clinical hold in the future.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States. In the European Union, the prevalence of the condition must not be more than 5 in 10,000. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. If a product that has orphan drug designation from the FDA subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a BLA, to market the same biologic

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

In *Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299 (11th Cir. 2021), the court disagreed with the FDA's longstanding position that the orphan drug exclusivity only applies to the approved use or indication within an eligible disease. This decision created uncertainty in the application of the orphan drug exclusivity. On January 24, 2023, the FDA published a notice in the Federal Register to clarify that while the agency complies with the court's order in *Catalyst*, FDA intends to continue to apply its longstanding interpretation of the regulations to matters outside of the scope of the *Catalyst* order – that is, the agency will continue tying the scope of orphan-drug exclusivity to the uses or indications for which a drug is approved, which permits other sponsors to obtain approval of a drug for new uses or indications within the same orphan designated disease or condition that have not yet been approved. It is unclear how future litigation, legislation, agency decisions, and administrative actions will impact the scope of the orphan drug exclusivity.

A company may request RMAT designation of its product candidate, which designation may be granted if the product meets the following criteria: (1) it is a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; (2) it is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (3) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition. RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate, and potential eligibility for rolling review and priority review. Products granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites post-approval, if appropriate. RMAT-designated products that receive accelerated approval may, as appropriate, fulfill their post- approval requirements through the submission of clinical evidence, clinical trials, 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 any such designation or eligibility will result in expedited review or approval or that the approved indication will not be narrower than the indication covered by the RMAT designation. Additionally, RMAT designation can be revoked if the criteria for eligibility cease to be met as clinical data emerges. On December 29, 2022, the Consolidated Appropriations Act, 2023, including the Food and Drug Omnibus Reform Act (FDORA), was signed into law. FDORA made several changes to the FDA's authorities and its regulatory framework, including, among other changes, reforms to the accelerated approval pathway, such as requiring the FDA to specify conditions for post-approval study requirements and setting forth procedures for the FDA to withdraw a product on an expedited basis for non-compliance with post-approval requirements. In March 2023, FDA issued a draft guidance on clinical trial considerations for supporting accelerated approval of oncology therapeutics, noting that although single-arm trials have been commonly used to support accelerated approval, a randomized controlled trial is the preferred approach for more robust efficacy and safety assessment. To the extent FDA requires us to amend the design of our clinical trials or requires additional trials to meet changes in the data requirements for approval, our clinical timelines and approval will be delayed, which can have an adverse effect on our business and operations.

We may pursue Breakthrough Therapy designation for one or more of our product candidates in the future. Even if granted by the FDA, such designation may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that the product candidate will receive marketing approval.

A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as breakthrough therapies, interaction and communication between

the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA are also eligible for priority review if supported by clinical data at the time of the submission of the BLA.

Although Breakthrough Designation or access to any other expedited program may expedite the development or approval process, it does not change the standards for approval. We may not experience faster development timelines or achieve faster review or approval compared to conventional FDA procedures. For example, the time required to identify and resolve issues relating to manufacturing and controls, the acquisition of a sufficient supply of our product for clinical trial purposes or the need to conduct additional nonclinical or clinical trials may delay approval by the FDA, even if the product qualifies for breakthrough designation or access to any other expedited program. Access to an expedited program may also be withdrawn by the FDA if it believes that the designation is no longer supported by data from our clinical development program. Additionally, qualification for any expedited review procedure does not ensure that we will ultimately obtain regulatory approval for such product candidate.

If approved, our investigational products regulated as biologics may face competition from biosimilars approved through an abbreviated regulatory pathway.

The ACA includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), which created an abbreviated approval pathway for biologic products that are biosimilar to or interchangeable with an FDA-licensed reference biologic 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 BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of the other company's product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty.

We believe that any of our product candidates approved as a biologic 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 investigational medicines 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 licensed, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biologic products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. If competitors are able to obtain regulatory approval for biosimilars referencing our products, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences.

Even if we receive regulatory approval of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require REMS as a condition of approving our product candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or foreign health authorities approve our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and record keeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with our product candidates, 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 our product candidates, withdrawal of the product from the market or voluntary or mandatory product recalls;
- Fines, warning letters or holds on clinical trials;
- Refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- Withdrawal of the drug from the market or voluntary or mandatory product recalls;
- Adverse publicity, fines, warning letters or holds on clinical trials;

•Product seizure or detention, or refusal to permit the import or export of our product candidates; and

•Injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

The FDA strictly regulates manufacturers' promotional claims of drug products. In particular, a drug product may not be promoted by manufacturers for uses that are not approved by the FDA, as reflected in the FDA-approved labeling, although healthcare professionals are permitted to use drug products for off-label uses. The FDA, the DOJ, the Inspector General of the Department of HHS, among other government agencies, actively enforce the laws and regulations prohibiting manufacturers' promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including large civil and criminal fines, penalties, and enforcement actions. The FDA has also imposed consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed for companies that engaged in such prohibited activities. If we cannot successfully manage the promotion of our approved product candidates, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions. Failure to obtain regulatory approval in foreign jurisdictions would prevent our product candidates from being marketed abroad.

In addition to regulations in the United States, to market and sell our products in the European Union, many Asian countries and other jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements, both from a clinical and manufacturing perspective. Approval by the FDA does not ensure approval by regulatory or payor authorities in other countries or jurisdictions, and approval by one regulatory or payor authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. A product candidate that has been approved for sale in a particular country may not receive reimbursement approval in that country. We may not be able to obtain approvals from regulatory authorities or payor authorities outside the United States on a timely basis, if at all.

We may also submit marketing applications in other countries, such as countries in Europe or Asia. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any jurisdiction. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain 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 are unable to obtain approval of any of our product candidates by regulatory or payor authorities in the European Union, Asia or elsewhere, or if we fail to comply with the regulatory requirements in foreign jurisdictions, the commercial prospects of that product candidate may be significantly diminished, and our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

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 product 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 fail to obtain and maintain required approvals, our ability to realize the full market potential of our products will be harmed.

The impact of recent healthcare reform legislation and other changes in the healthcare industry and in healthcare spending on us is currently unknown, and may adversely affect our business model.

Our revenue prospects could be affected by changes in healthcare spending and policy in the United States and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare, including proposals aimed at lowering prescription drug prices and increasing competition for prescription drugs, as well as additional regulation on pharmaceutical transparency and reporting requirements, any of which could negatively impact our future profitability and increase our compliance burden. We cannot predict the initiatives that may be adopted in the future, including future challenges or significant revisions to the ACA. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- The demand for our product candidates, if we obtain regulatory approval;
- Our ability to set a price that we believe is fair for our products;
- Our ability to obtain coverage and reimbursement approval for a product;
- Our ability to generate revenue and achieve or maintain profitability;
- The level of taxes that we are required to pay; and
- The availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

Risks Related to Commercialization of Our Product Candidates

Even if we obtain regulatory approval of our product candidates, the products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers and others in the medical community.

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, existing cell therapies are currently offered only in tertiary academic hospitals that have intensive care units that can support the safety and toxicity issues associated with cell therapies. If we are unable to demonstrate sufficient safety to permit a broader use of our product candidates, 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:

- The clinical indications for which our product candidates are approved;
- The willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- Physicians, hospitals, cancer treatment centers and patients considering our product candidates as a safe, pure and effective treatment;
- The potential and perceived advantages of our product candidates over alternative treatments;
- Our ability to demonstrate the advantages of our product candidates over other conventional CAR-T therapies;
- The perceived prevalence and severity of any side effects for our product candidates compared to the prevalence and severity of any side effects for conventional CAR-T products and other cell therapies;
- Product labeling, limitations, warnings or product insert requirements of the FDA or foreign health authorities;

•The timing of market introduction of our product candidates as well as competitive products;

•The cost of treatment in relation to alternative treatments;

•The availability of adequate coverage, reimbursement and pricing by third-party payors and government authorities;

•The willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors and government authorities;

•Relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and

•The effectiveness of our sales and marketing efforts.

If our product candidates are approved but fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers or others in the medical community, we will not be able to generate significant revenue.

Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

We may face difficulties from changes to current regulations and future legislation. Current and future legislation may increase the difficulty and cost for us to commercialize our drugs, if approved, and affect the prices we may obtain, including changes in coverage and reimbursement policies in certain market segments for our product candidates, which could make it difficult for us to sell our product candidates, if approved, profitably.

Existing regulatory policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability. In both domestic and foreign markets, successful sales of our product candidates, if approved, will depend on the availability of adequate coverage and reimbursement from third-party payors. In addition, because our product candidates represent novel approaches to the treatment of cancer and autoimmune diseases, we cannot accurately estimate the potential revenue from our product candidates.

Patients who receive medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor’s determination that use of a product is:

•A covered benefit under its health plan;

•Medically necessary and has acceptable risk-benefit ratio;

•Appropriate for the specific patient;

•Cost-effective; and

•Neither experimental nor investigational.

Obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our products. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Due to the high costs associated with cell therapies, patients are unlikely to use our product candidates unless coverage is provided or reimbursement is adequate to cover a significant portion of the cost of our product candidates.

In the United States, no uniform policy of coverage and reimbursement for products exists among third- party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

We intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the European Union, the pricing of biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidates and may be affected by existing and future healthcare reform measures.

The ACA made extensive changes to the delivery of health care in the United States. We expect that the rebates, discounts, taxes and other costs resulting from the ACA over time will have a negative effect on our expenses and profitability in the future. The ACA contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. For example, the ACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by increasing the minimum basic Medicaid rebate on most branded prescription drugs. Additionally, for a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program.

Since the enactment of the ACA, there have been judicial and Congressional challenges to certain aspects of the ACA. In June 2021, the United States Supreme Court held that Texas and other challengers had no legal standing to challenge the ACA, dismissing the case without specifically ruling on the constitutionality of the ACA. Accordingly, the ACA remains in effect in its current form. It is unclear how this Supreme Court decision, future litigation, or healthcare measures promulgated by the Biden administration will impact our business, financial condition and results of operations. Complying with any new legislation or changes in healthcare regulation could be time-intensive and expensive, resulting in material adverse effect on our business.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, the Budget Control Act of 2011, among other things, included reductions to CMS payments to providers of 2% per fiscal year, which went into effect in 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2031, with the exception of a temporary suspension implemented under various COVID-19 relief legislation. The Consolidated Appropriations Act of 2023 extended the 2% Medicare sequester for the first six months of fiscal year 2032 and revised the sequester percentage up to 2% for fiscal year 2030 and 2031. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012 (the ATRA), which, among other things, reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover over payments to providers from three to five years. Legislators, regulators and third-party payers may continue to put forth proposals to reduce costs while expanding individual healthcare benefits, including proposals that impose additional limitations on the rates we will be able to charge for our product candidates, if approved, or the amount of reimbursement available for such approved products from governmental agencies or third-party payers. Current and future healthcare reform legislation and policies could have a material adverse effect on our business and financial condition. We cannot predict what other health care programs and regulations will ultimately be implemented at the federal or state level or the effect of any future legislation or regulation in the United States may have on our business.

There has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products.

For example, under the American Rescue Plan Act of 2021, effective January 1, 2024, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs will be eliminated. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have a material impact on our business. Further, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at increasing competition for prescription drugs. In response to this executive order, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and potential legislative policies that Congress could pursue to advance these principles. In August 2022, Congress passed the Inflation Reduction Act of 2022, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. Various industry stakeholders, including pharmaceutical companies, the U.S. Chamber of Commerce, the National Infusion Center Association, the Global Colon Cancer Association, and the Pharmaceutical Research and Manufacturers of America, have initiated lawsuits against the federal government asserting that the price negotiation provisions of the Inflation Reduction Act are

unconstitutional. The impact of these judicial challenges as well as future legislative, executive, and administrative actions and agency rules implemented by the government on us and the pharmaceutical industry as a whole is unclear. The implementation of cost containment measures, including the prescription drug provisions under the Inflation Reduction Act, as well as other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates if approved. Complying with any new legislation and regulatory changes could be time-intensive and expensive, resulting in a material adverse effect on our business.

At the state level, individual states are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. For example, a number of states are considering or have recently enacted state drug price transparency and reporting laws that could substantially increase our compliance burdens and expose us to greater liability under such state laws once we begin commercialization after obtaining regulatory approval for any of our products. These measures could reduce the demand for our products, if approved, or impose additional pricing pressures on how much we can charge for our products if approved.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-approval testing and other requirements.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or in other jurisdictions. If we or our collaborators are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or our collaborators are not able to maintain regulatory compliance, our product candidates may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

We currently have no sales organization and have a limited marketing organization and limited experience in marketing cell therapy products. If we are unable to establish adequate marketing and sales capabilities or establish or maintain relationships with third parties to market and sell our product candidates, if approved, we may not be able to generate product revenue.

We currently have no sales or distribution capabilities and have limited marketing capabilities and limited experience in marketing cell therapy products. If any of our product candidates ultimately obtains regulatory approval, we, whether alone or with Kite for programs that we commercialize together, may not be able to effectively or successfully market the approved product.

For any approved product for which we share co-commercialization and co-promotion responsibilities, we may experience challenges, costs or other issues in having to work together with our collaborators. Our inability to work together to successfully market and sell any such products could have a material adverse effect on our business and overall financial condition.

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 relying on 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. By relying on third parties for such activities, we may have little or no control over the marketing and sales efforts conducted on our behalf and our revenue from product sales may be lower than if we had commercialized our product candidates in-house. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates and may have difficulties maintaining the relationships already established.

There can be no assurance that we will be able to develop adequate in-house sales and distribution capabilities or establish or maintain successful relationships with third-party collaborators to commercialize any product in the United States or abroad.

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

We may be subject to or affected by data protection laws and regulations, such as laws and regulations that address privacy and data security. In the United States, numerous federal and state laws and regulations, including federal and state health information privacy laws, state data breach notification laws, and federal and state consumer protection laws, such as Section 5 of the Federal Trade Commission Act, govern the collection, use, disclosure and protection of health information and other personal information could apply to our operations. 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, and its implementing rules and regulations. Depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

In addition, the California Consumer Privacy Act ("CCPA") took effect in January 2020 and became enforceable in July 2020. The CCPA created new individual privacy rights for California consumers (as the word is broadly defined in the law) and placed increased privacy and security obligations on many organizations that handle personal information of consumers or households. The CCPA requires covered companies to provide disclosures to consumers about such companies' data collection, use and sharing practices, and to provide such consumers a right to opt-out of certain sales or transfers of personal information, and provides consumers with a new cause of action for certain data breaches. Additionally, California voters voted to approve the California Privacy Rights Act ("CPRA") in November 2020, which modifies the CCPA significantly, with most modifications going into effect January 1, 2023. The CPRA has created further uncertainty and has required, and may require, us to incur additional costs and expenses in an effort to comply. Many similar privacy laws have been enacted or proposed at the federal level and in other states. For example, Virginia, Colorado, Utah and Connecticut all have enacted general privacy legislation that has become, or will become, effective in 2023; Florida, Montana, Oregon, and Texas have enacted similar legislation that becomes effective in 2024; Delaware, Iowa, and Tennessee have enacted similar legislation that becomes effective in 2025; and Indiana has enacted similar legislation that becomes effective in 2026. The CCPA, CPRA, and other new and evolving legislation may increase our compliance costs and potential liability.

Compliance with data protection laws and regulations could require us to take on more onerous obligations in our contracts, increase our costs of legal compliance, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with data protection laws and regulations could result in government investigations and/or enforcement actions (which could include civil, criminal, and administrative penalties), private litigation 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.

A variety of risks associated with seeking regulatory approval for and marketing our product candidates internationally could materially adversely affect our business.

We plan to seek regulatory approval of our product candidates outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- Differing regulatory requirements in foreign countries, including constraints on manufacturing;
- Additional trials in foreign countries;
- Requirement to secure and validate region-specific manufacturing and clinical and commercial supply;
- Unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- Economic weakness, including inflation, or political instability in particular foreign economies and markets;
- Compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- Foreign taxes, including withholding of payroll taxes;
- Foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- Difficulties staffing and managing foreign operations;

•Workforce uncertainty in countries where labor unrest is more common than in the United States;

•Potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;

•Challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;

•Production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and

•Business interruptions resulting from geo-political actions, including war (including ongoing geopolitical tensions related to Russia's actions in Ukraine, resulting sanctions imposed by the United States and other countries, and retaliatory actions taken by Russia in response to such sanctions), armed conflict, terrorist activities, global pandemics and terrorism.

These and other risks associated with our international operations, including relating to data privacy and security, may materially adversely affect our ability to attain or maintain profitable operations.

The European Union system for authorization of medicinal products for human use offers several routes: the centralized procedure, the decentralized procedure, and the mutual recognition procedure, as well as domestic national routes. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union Member States as well as the European Economic Area ("EEA") countries of Iceland, Liechtenstein and Norway. The centralized procedure is mandatory for certain categories of investigational products, including human products containing a new active substance indicated for the treatment of certain diseases, including cancer, AIDS, diabetes and neurodegenerative illness; orphan medicinal products; and medicinal products manufactured using biotechnological processes. Applications for marketing authorization for such medicines must be submitted to the European Medicines Agency ("EMA"), in which the Committee for Medicinal Products for Human Use ("CHMP") is generally responsible for conducting the initial assessment of a product.

The decentralized and mutual recognition procedures are applicable to the majority of conventional medicinal products and are both based on the principle of recognition of a marketing authorization by one or more Member States. Any national marketing authorization granted by a European Union Member State's national authority can be used to support an application for its mutual recognition by other Member States. Marketing authorization applications can also be submitted directly to the Member State's national competent authority under the national route (if the centralized route is not compulsory). Following Brexit, there are now multiple routes to obtain a marketing authorization in the United Kingdom, Great Britain or Northern Ireland, including national routes and international routes. The application procedure will depend on the relevant procedure chosen. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, may force us to restrict or delay efforts to seek regulatory approval in the United Kingdom for our product candidates, which could significantly and materially harm our business. Further, even after obtaining market authorization, differences in GMP, pharmacovigilance, and other regulatory requirements in different jurisdictions can increase our compliance costs and exposure to potential liability.

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, 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 and the ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes 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 the SEC and other government agencies on which our operations may rely, including those 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, such as recent furloughs or government shutdowns, may also increase the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business.

Separately, in response to the COVID-19 pandemic, since March 2020 when foreign and domestic inspections of facilities were largely placed on hold, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. In 2020 and 2021, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. While the FDA has largely caught up with domestic pre-approval inspections, it continues to work through its backlog of foreign inspections. However, the FDA may not be able to continue its current pace and review timelines could be extended, including delays due to the COVID-19 pandemic, travel restrictions, or staffing shortages, any of which may cause the FDA to be unable to complete such required inspections during the review period. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. If a prolonged government shutdown or other disruption occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material

adverse effect on our business. Future shutdowns or other disruptions could also affect other government agencies such as the SEC, which may also impact our business by delaying review of our public filings, to the extent such review is necessary, and our ability to access the public markets.

Regulatory authorities outside the United States may also impose similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Our business activities may be subject to the Foreign Corrupt Practices Act and similar anti-bribery and anti- corruption laws, as well as U.S. and certain foreign export controls, trade sanctions, and import laws and regulations, all of which can subject us to criminal liability and other serious consequences for violations.

Our business activities may be subject to the U.S. Foreign Corrupt Practices Act (the "FCPA"), and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. These laws generally prohibit companies and their employees and third-party business partners, representatives and agents from engaging in corruption and bribery, including offering, promising, giving or authorizing the provision of anything of value, either directly or indirectly, to a government official or commercial party in order to influence official action, direct business to any person, gain any improper advantage, or obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with government officials, including potentially officials of non-U.S. governments.

Additionally, in many countries, healthcare providers are employed by the government, and the purchasers of biopharmaceuticals are government entities. As a result, our dealings with these providers and purchasers are subject to regulation and such healthcare providers and employees of such purchasers may be considered "foreign officials" as defined in the FCPA. Recently, the SEC and the DOJ have increased their FCPA enforcement activities with respect to biotechnology companies. In addition to our own employees, we may in the future leverage third parties to conduct our business abroad, such as obtaining government licenses and approvals. We and our third-party business partners, representatives and agents may have direct or indirect interactions with officials and employees of government agencies, state-owned or affiliated entities and we may be held liable for the corrupt or other illegal activities of our employees, our third-party business partners, representatives and agents, even if we do not explicitly authorize such activities. There is no certainty that our employees or the employees of our third-party business partners, representatives and agents will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in whistleblower complaints, adverse media coverage, investigations, loss of export privileges, debarment from U.S. government contracts, substantial diversion of management's attention, significant legal fees and fines, severe criminal or civil sanctions against us, our officers, or our employees, disgorgement and other sanctions and remedial measures, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, financial condition and stock price.

Furthermore, our products may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our products, or our failure to obtain any required import or export authorization for our products, when applicable, could harm our business. Moreover, U.S. export control laws and economic sanctions prohibit the provision of certain products and services to countries, governments, and persons targeted by U.S. sanctions. U.S. sanctions that have been or may be imposed as a result of military conflicts in other countries may impact our ability to conduct activities at clinical trial sites within regions covered by such sanctions. For example, as a result of Russia's actions in Ukraine, the United States and its European allies have imposed sanctions on certain industry sectors and parties in Russia and the regions of Donetsk and Luhansk in Ukraine, as well as enhanced export controls on certain products and industries. These and any additional sanctions and export controls, as well as any economic countermeasures by the governments of Russia or other jurisdictions, could adversely impact our ability to continue activities at clinical trial sites within regions covered by such sanctions or directly or indirectly disrupt our supply chain. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges.

Risks Related to Ownership of our Common Stock

We do not know whether an active, liquid, and orderly trading market will be sustained for our common stock.

Prior to our initial public offering, there was no public trading market for shares of our common stock. Although our common stock is listed on the Nasdaq Global Select Market, the market for our shares has demonstrated varying levels of trading activity. It is possible that in one or more future periods our results of operations and progression of our product pipeline may not meet the

expectations of public market analysts and investors, and, as a result of these and other factors, the levels of trading activity may decline. You may not be able to sell your shares quickly or at the market price if trading in shares of our common stock is not active. The lack of an active market may also reduce the fair market value of your shares. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of our common stock as consideration.

The price of shares of our common stock may be volatile and may be adversely impacted by future events, and you could lose all or part of your investment.

The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, many of which are beyond our control, including limited trading volume. In addition to the factors discussed in this Risk Factors section, and elsewhere in this Quarterly Report on Form 10-Q, these factors include:

- Our decision to initiate a clinical trial, not to initiate a clinical trial, or to terminate an existing clinical trial;
- The commencement, enrollment, or results of the clinical trials of our product candidates or any future clinical trials we may conduct, or changes in the development status of our product candidates;
- Results from ongoing clinical trials and future clinical trials of our competitors;
- Any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- Our failure to achieve product development goals in the time frames we announce;
- Adverse results or delays in clinical trials;
- Adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- Changes in laws or regulations applicable to our product candidates, including, but not limited to, clinical trial requirements for approvals;
- Adverse developments concerning our manufacturers;
- Our inability to obtain adequate supply for any product candidate, or any component thereof, or approved product or inability to do so at acceptable prices;
- Our inability to establish collaborations if needed;
- Our failure to commercialize our product candidates;
- Unanticipated serious safety concerns related to the use of our product candidates;
- Introduction of new products or other therapies offered by us or our competitors;
- Announcements of significant acquisitions, strategic partnerships, joint ventures, or capital commitments by us or our competitors;
- Additions or departures of key scientific or management personnel;
- Our ability to effectively manage our growth;
- The size and growth of our initial cancer target markets;
- Our ability to successfully treat additional types of cancers or at different stages;
- Actual or anticipated variations in quarterly operating results;
- Our cash position;
- Our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- Publication of research reports about us or our industry, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- Changes in the market valuations of similar companies;
- Our operating performance and the performance of other similar companies;

•Overall performance of the equity markets;

•The expiration of market stand-off or contractual lock-up agreements;

•Sales of our common stock by us or our stockholders in the future;

•Trading volume of our common stock;

•Changes in accounting practices;

•Ineffectiveness of our internal controls;

•Disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;

•Significant lawsuits, including patent or stockholder litigation;

•General political and economic conditions, including the impact of the COVID-19 global pandemic and the ongoing geopolitical tensions related to Russia's actions in Ukraine, resulting sanctions imposed by the United States and other countries, and retaliatory actions taken by Russia in response to such sanctions; and

•Other events or factors, many of which are beyond our control.

In addition, the stock market in general, and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock relies in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

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

Our executive officers, directors, and holders of 5% or more of our capital stock and their respective affiliates beneficially own a significant amount of our outstanding voting stock. Therefore, these stockholders, if they act together, will have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interests as one of our stockholders. Further, the significant concentration of stock ownership may adversely affect the market price of our common stock due to investors' perception that conflicts of interest may exist or arise.

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

We are currently an emerging growth company, as defined in the Jumpstart Our Business Startups Act (JOBS Act) enacted in April 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended (Sarbanes-Oxley Act), reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We also currently qualify as a "smaller reporting company," which allows us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act (if we have less than $100 million in annual revenues in our most recent fiscal year), being able to present only the two most recent fiscal years of audited financial statements and reduced disclosure obligations regarding executive compensation

in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may 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.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to use this extended transition period 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. As a result, changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance, or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations and make our common stock less attractive to investors.

On the last business day of our second quarter in 2023, the aggregate market value of our shares held by non-affiliate stockholders exceeded $700 million. As a result, as of December 31, 2023, we will be considered a large accelerated filer as defined in Rule 12b-2 under the Exchange Act, and we will cease to be an emerging growth company as defined in the JOBS Act. We will no longer be exempt from the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, and our independent registered public accounting firm will evaluate and report on the effectiveness of internal control over financial reporting. We will also no longer be permitted to take advantage of reduced reporting requirements for smaller reporting companies. We expect to incur significant costs as a result of complying with additional compliance and reporting requirements, and our management and other personnel will need to devote a substantial amount of time to ensure that we comply with additional reporting requirements. Such initiatives and requirements will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all.

We will no longer qualify as an “emerging growth company” or a "smaller reporting company" as of December 31, 2023 and, as a result, we will no longer be able to avail ourselves of certain reduced reporting requirements applicable to emerging growth companies or smaller reporting companies, subject to applicable transition relief.

We are currently an “emerging growth company,” as defined in the JOBS Act, and we have taken advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not “emerging growth companies,” including the auditor attestation requirements of Section 404, compliance with requirements that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditors’ report providing additional information about the audit and the financial statements, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. In addition, as an emerging growth company, we have elected to use the extended transition period for complying with new or revised accounting standards until those standards would otherwise apply to private companies. 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.

Because the market value of our common stock held by non-affiliates exceeded $700 million as of June 30, 2023, we will be deemed a large accelerated filer under the Exchange Act and will lose our status as an “emerging growth company” as of December 31, 2023. As a result of our loss of “emerging growth company” status, it is possible that investors will find our common stock less attractive in light of the fact that we have relied on certain of 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 share price may be more volatile. In addition, any failure to comply with these additional requirements in a timely manner, or at all, could have an adverse effect on our business and results of operations and could cause a decline in the price of our common stock.

We have incurred and will continue to incur significant increased costs as a result of operating as a public company, and our management has devoted and will continue to devote substantial time and resources to new compliance initiatives.

As a public company, and particularly after we are no longer an emerging growth company or a smaller reporting company, we have incurred and will continue to incur significant legal, accounting, and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (Exchange Act), which require, among other things, that we file with the SEC annual, quarterly, and current reports with respect to our business and financial condition. Compliance with the various reporting and other requirements applicable to public companies requires considerable time and attention of management. We cannot assure you that we will satisfy our obligations as a public company on a timely basis.

In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and the Nasdaq Stock Market (Nasdaq) to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further,

in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act (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 emerging growth companies to implement many of these requirements over a longer period and up to five years from the pricing of our initial public offering. We intend to take advantage of this 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. On the last business day of our second quarter in 2023, the aggregate market value of our shares held by non-affiliate stockholders exceeded $700 million. As a result, as of December 31, 2023, we will be considered a large accelerated filer as defined in Rule 12b-2 under the Exchange Act, and we will cease to be an emerging growth company as defined in the JOBS Act. We will no longer be exempt from the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, and our independent registered public accounting firm will evaluate and report on the effectiveness of internal control over financial reporting. We will also no longer be permitted to take advantage of reduced reporting requirements for smaller reporting companies. We expect to incur significant costs as a result of complying with additional compliance and reporting requirements, and our management and other personnel will need to devote a substantial amount of time to ensure that we comply with additional reporting requirements. Such initiatives and requirements will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all.

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act and regulations implemented by the SEC and Nasdaq may increase legal and financial compliance costs and make some activities more time consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We have invested and intend to continue to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management’s time and attention from product development activities to compliance activities. The rules and regulations applicable to public companies have increased substantially and will continue to increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition, and results of operations. The increased costs will decrease our net income or increase our net loss and may require us to reduce costs in other areas of our business or increase the prices of our products or services. 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 the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees, or as executive officers.

We use significant assumptions and judgment in evaluating whether our CMO and CDMO agreements is or contains a lease, and failure to adequate account for these contracts, or changes to such contracts, may harm our results of operations.

We enter into manufacturing supply agreements with CMOs and CDMOs to manufacture clinical product candidate materials. Such agreements may include an embedded lease due to the exclusive use of identified manufacturing facilities and equipment that are controlled by us and for which we obtain substantially all the output. We use significant assumptions and judgment in evaluating our lease contracts and other agreements, including the determination of whether an agreement is or contains a lease, whether a change in the terms and conditions of a lease contract represent a new or modified lease, whether a lease represents an operating or finance lease, the discount rate used to determine the present value of lease obligations, and the term of a lease embedded in our manufacturing supply agreements.

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

We expect that significant additional capital may be needed in the future to continue our planned operations, which include conducting clinical trials, pursuing commercialization efforts, expanding research and development activities, and continuing to operate as a public company. To raise capital, 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, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences, and privileges senior to the holders of our common stock, including shares of common stock sold in our initial public offering. If we raise additional funds through up-front payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to our drug candidates, or grant licenses on terms that are not favorable to us.

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. Pursuant to the 2022 Equity Incentive Plan (the "2022 Plan"), our board of directors or its duly authorized committee is authorized to grant equity awards to our employees, directors, and consultants.

Initially, the aggregate number of shares of our common stock that was able to be issued pursuant to equity awards under the 2022 Plan was 4,296,875 shares, plus the number of shares subject to awards granted under our 2017 Equity Incentive Plan (the "2017 Plan") that expire or otherwise terminate without having been exercised in full or are forfeited to or repurchased by us (provided that the maximum number of shares that could (and can) be added to the 2022 Plan pursuant to awards under the 2017 Plan is 6,269,300). The number of shares of our common stock reserved for issuance under the 2022 Plan is cumulatively increased on the first day of each fiscal year, which began with our 2023 fiscal year and will end on the ten year anniversary of the date our board of directors approved the 2022 Plan equal to the *least* of (i) 4,296,875 shares, (ii) 5.0% of the total number of shares of our common stock outstanding as of the last day of the immediately preceding fiscal year, or (iii) a number of shares determined by the administrator of the 2022 Plan. As a result of the 2022 Plan, our stockholders may experience additional dilution. On January 1, 2023, the number of shares available for issuance under the 2022 Plan was increased by 2,205,299 additional shares.

Pursuant to our 2022 ESPP, our employees may receive the right to purchase shares of our common stock. Initially, the aggregate number of shares of our common stock available for sale under our 2022 ESPP was 312,500 shares. The number of shares of our common stock available for sale under our 2022 ESPP is cumulatively increased on the first day of each fiscal year, beginning with the fiscal year following the fiscal year in which the first enrollment date (if any) occurs under the 2022 ESPP, which occurred in the Company's 2022 fiscal year, and ending on the twenty-year anniversary of the date our board of directors approved the 2022 ESPP equal to the *least* of: (i) 312,500 shares, (ii) 1.0% of the total number of shares of our common stock outstanding as of the last day of the immediately preceding fiscal year, or (iii) a number of shares determined by the administrator of the 2022 ESPP. As a result of the 2022 ESPP, our stockholders may experience additional dilution. On January 1, 2023, the number of shares available for issuance under the 2022 ESPP was increased by 312,500 additional shares.

If we fail to establish and maintain proper and effective internal controls over financial reporting, our operating results and our ability to operate our business could be harmed.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be evaluated frequently. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. We have begun the process of documenting, reviewing, and improving our internal controls and procedures for compliance with Section 404 of the Sarbanes- Oxley Act, which will require annual management assessment of the effectiveness of our internal control over financial reporting. We continue to recruit additional finance and accounting personnel with certain skill sets that we will need as a public company.

Implementing any appropriate changes to our internal controls may distract our officers and employees, entail substantial costs to modify our existing processes, and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and harm our business. We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our consolidated financial statements. Our internal controls 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. In addition, investors' perceptions that our internal controls are inadequate or that we are unable to produce accurate financial statements on a timely basis may harm our stock price and make it more difficult for us to effectively market and sell our service to new and existing customers.

If we are unable to maintain effective disclosure controls and procedures, our business, financial position and results of operations could be adversely affected.

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. Management concluded that our disclosure controls and procedures were not effective at the reasonable assurance level as of the end of each of the quarters ended March 31, 2022 and June 30, 2022 due to a material weakness in our internal control over financial reporting as of such dates. This material weakness has been remediated as of December 31, 2022.

These inherent limitations include the facts that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. 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.

We do not intend to pay dividends on our common stock, so any returns will be limited to the capital appreciation of our stock.

You should not rely on an investment in our common stock to provide dividend income. We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation, and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, the terms of any future debt agreements may preclude us from paying dividends. Any return to stockholders will therefore be limited to the appreciation of their stock, which may never occur.

Certain provisions under our charter documents and Delaware law could delay or prevent a change of control, which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could discourage, delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- A board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time, which could delay the ability of stockholders to change the membership of a majority of our board of directors;
- 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, disqualification or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- A prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at an annual or special meeting of our stockholders;
- A requirement that special meetings of stockholders be called only by the chairperson of our board of directors, our Chief Executive Officer, our President, or our board of directors acting pursuant to a resolution adopted by a majority of our board of directors, which could delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors;
- Advance notice requirements for stockholder proposals and nominations for election to our board of directors, 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;
- A requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than a majority of the shares present in person or by proxy at the meeting and entitled to vote, which could delay the ability of stockholders to change the membership of our board of directors;
- A requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation, which may inhibit the ability of an acquirer to affect such amendments to facilitate an unsolicited takeover attempt; and
- The authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval, which preferred stock may include rights superior to the rights of the holders of common stock and could be used to significantly dilute the ownership of a hostile acquirer.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. 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 anti-takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer, or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline and limit opportunities for you to realize value in a corporate transaction.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America are the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another state court in Delaware) is the exclusive forum for the following (except for any claim as to which such court determines that there is an indispensable party not subject to the jurisdiction of such court (and the indispensable party does not consent to the personal jurisdiction of such court within 10 days following such determination), which is vested in the exclusive jurisdiction of a court or forum other than such court or for which such court does not have subject matter jurisdiction):

•Any derivative action or proceeding brought on our behalf;

•Any action asserting a claim of breach of fiduciary duty;

•Any action asserting a claim against us arising under the Delaware General Corporation Law (DGCL), our amended and restated certificate of incorporation or our amended and restated bylaws; and

•Any action asserting a claim against us that is 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 or any other claim for which the U.S. federal courts have exclusive jurisdiction.

Our amended and restated bylaws further provide 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. For the avoidance of doubt, this provision shall not apply to any claim brought to enforce a duty or liability created by the Exchange Act.

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. Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions. There is uncertainty as to whether a court would enforce such provisions, and the enforceability of similar choice of forum provisions in other companies' charter documents has been challenged in legal proceedings. It is possible that a court could find these types of provisions to be inapplicable or unenforceable, and if a court were to find either exclusive-forum provision in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business.

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, operating results, or financial condition.

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

(a) Sales of Unregistered Securities

There were no sales of unregistered securities by us during the quarter ended September 30, 2023 that were not previously reported in current reports on Form 8-K filed with the SEC.

(b) Use of Proceeds from Public Offering of Common Stock

On February 8, 2022, we closed our IPO, in which we issued and sold 9,487,500 shares of common stock, including the exercise in full by the underwriters of their option to purchase up to 1,237,500 additional shares of common stock, at a public offering price of $15.00 per share. We received net proceeds of $127.3 million, after deducting underwriting discounts and commissions and other offering expenses paid by us of approximately $15.0 million. All of the shares of common stock issued and sold in our initial public offering were registered under the Securities Act of 1933, as amended, or the Securities Act, pursuant to a registration statement on Form S-1 (Registration No. 333-262191), which was declared effective by the SEC on February 3, 2022. BofA Securities, Inc., SVB Securities LLC, Barclays Capital Inc. and William Blair & Company, L.L.C. acted as representatives of the several underwriters of the IPO. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning 10% or more of any class of our equity securities or to any other affiliates. There has been no material change in the planned use of IPO proceeds from that described in our final prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on February 7, 2022.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

We are providing the following disclosure in lieu of filing a Current Report on Form 8-K relating to Item 1.01 (Entry into a Material Definitive Agreement):

On September 1, 2023, we signed Amendment 1 to the Lonza SOW entered into in February 2022. Amendment 1 increased quantity of manufacturing slots from September 2023 through the end of the lease in December 2024 and increased the amount of capacity and equipment exclusively controlled by us.

These changes under Amendment 1 were accounted for as a lease modification, and we remeasured the lease liabilities for the modified lease as of the Amendment effective date. The remeasurement of the lease liabilities included fixed consideration with an undiscounted value of approximately $51.7 million, or $48.5 million discounted using the expected payment timeline and the incremental borrowing rate of 10.8%. This resulted in an increase of $15.9 million in lease liabilities. As we acquired ROU assets that represented assets acquired for research and development activities that did not have an alternative future use, we recorded the ROU assets as R&D expense immediately.

The foregoing description of the Amendment 1 to the Lonza SOW is not complete and is subject to, and qualified in its entirety by reference to, the Amendment 1 to the Lonza SOW, a copy of which is filed with this Form 10-Q as Exhibit 10.1 and incorporated herein by reference.

Item 6. Exhibits

The exhibits listed on the Exhibit Index immediately preceding such exhibits, which is incorporated herein by reference, are filed or furnished as part of this Quarterly Report.

Exhibit	Description of Document	Filed Herewith	Incorporated by Reference	Form	Exhibit Number	Filing Date
3.1	Amended and Restated Certificate of Incorporation of the Registrant, as amended, as currently in effect.		X	10-Q	3.1	8/14/2023
3.2	Second Amended and Restated Bylaws of the Registrant, as currently in effect.		X	8-K	3.1	12/16/2022
3.3	Certificate of Amendment of the Amended and Restated Certificate of Incorporation of the Registrant, dated June 14, 2023		X	10-Q	3.3	8/14/2023
4.1	Amended and Restated Investors' Rights Agreement among the Registrant and certain of its stockholders, dated March 26, 2021.		X	S-1	4.1	1/14/2022
4.2	Specimen common stock certificate of the Registrant.		X	S-1/A	4.2	1/31/2022
10.1^	Amendment No.1 to Statement of Work A-1 between Registrant and Lonza Houston, Inc. dated February 16, 2022	X				
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X				
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X				
32.1†	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X				
32.2†	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X				
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.	X				
101.SCH	Inline XBRL Taxonomy Extension Schema Document.	X				
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.	X				
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.	X				
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.	X				
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.	X				
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).	X				

† The certifications attached as Exhibit 32.1 and 32.2 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.
^ Portions of this exhibit have been omitted in accordance with Item 601 of Regulation S-K.

SIGNATURE

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.

Arcellx, Inc.

Date: November 13, 2023

By: /s/ Michelle Gilson
Michelle Gilson
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 10.1

[CERTAIN INFORMATION IN THIS EXHIBIT IDENTIFIED BY [***] IS CONFIDENTIAL AND HAS BEEN EXCLUDED BECAUSE IT (I) IS NOT MATERIAL AND (II) THE REGISTRANT CUSTOMARILY AND ACTUALLY TREATS THAT INFORMATION AS PRIVATE OR CONFIDENTIAL.]

Amendment 1 to Statement of Work A-1

Increased Demand from September 2023 Through December 2024

This Amendment 1 to Statement of Work A-1 ("Amendment 1") is entered into September 1st, 2023 (the "Amendment 1 Effective Date") by and between Arcellx, Inc. ("Arcellx" or the "Client") and LONZA Houston, Inc. ("LONZA") pursuant to the Manufacturing Services Agreement dated 02 September 2021 by and between Client and LONZA (the "Agreement"), amends Statement of Work A-1 made effective as of February 16, 2022 ("SOW A-1") and entered into under the Agreement, and is incorporated into and made a part of and governed by such Agreement and SOW A-1. In the event of an inconsistency between the Agreement and this Amendment 1, the Agreement shall control unless otherwise specifically stated below.

All capitalized terms used in this Amendment 1 shall have the meanings ascribed to them in the Agreement or SOW A-1, as applicable, unless otherwise indicated.

WHEREAS, the Parties desire to amend Statement of Work A-1 by agreeing to this Amendment 1.

NOW, THEREFORE, in consideration of the above premises and the mutual covenants herein set forth, the Parties hereby agree as follows:

1.Section 4.4 ("cGMP Manufacturing") of SOW A-1 is hereby amended by adding the following at the end of the sub-Section titled "Manufacturing Schedule":

As of the Amendment 1 Effective Date, the Manufacturing Schedule of original SOW A-1 shall be amended by replacing it with the following revised "Amendment 1 Manufacturing Schedule":

Amendment 1 Manufacturing Schedule:

a.Following the Amendment 1 Effective Date, Lonza will provide [***] suites in which to manufacture Product ("[***]") to meet Client's estimated demand as set forth in detail below.

i.Lonza will provide manufacturing slots per month in accordance with the Manufacturing Plan provided below, subject to adjustments in accordance with the provisions of this paragraph (a)(i).

Client may request additional slots for any given month, up to a maximum number of slots in any given month of [***], by providing at least [***] advanced written notice of such increase for the applicable month. Lonza will use Commercially Reasonable Efforts, [***].

Subject to the adjustments set forth above, Client shall be obligated to [***] (subject to the requirements set forth in (a)(ii)) [***] pursuant to the Manufacturing Plan below, as may be modified via Client request pursuant to the above, [***].

[***] will be utilized [***] for manufacturing Client's Product through the remainder of the term of SOW A-1.

The manufacturing will follow the schedule below, unless updated per Client request pursuant to the above.

Manufacturing Plan:

[***]

If Lonza fails to provide the capacity as set forth in the Manufacturing Plan, accounting for any adjustment pursuant to this paragraph (a)(i), other than to the extent that such failure to provide capacity resulted from (i) Client causing a slot to not be available, (ii) a shutdown occurring in accordance with paragraph (c) under the heading "Amendment 1 Manufacturing Schedule" of this Amendment 1 or (iii) reasons outside the reasonable control of Lonza, and subject to SOW A-1 Sections 7 and 8, Client shall [***] to reflect the capacity actually provided. If Lonza fails to provide the capacity as set forth above, accounting for any adjustment pursuant to this paragraph (a)(i), and [***].

ii.Lonza will offer the manufacturing dates for each slot by a minimum of [***] prior to the start of the manufacturing month. Client may use an offered slot [***]. Client shall confirm if Client wishes to use an applicable offered slot for [***] with a minimum of [***] written notice prior to the manufacturing commencement of a Batch in such offered slot (except with respect to Batches where Lonza is providing Starting Material, in which case Client must provide at least [***] written notice prior to the manufacturing commencement of that Batch). Client may separately choose, on an *ad hoc* basis and via confirmation in writing at least [***] prior to the manufacturing commencement of a Batch, to use an offered slot for another type of run ([***]).

iii.Lonza will prepare the released Product for shipment to the clinical site within [***] of the lot release provided that Client provides [***] written notice to Lonza for the shipment request.

b.The manufacturing model assumes the following:

i.[***].

ii.When possible, Client will ship Starting Material in time for Lonza to receive it [***] prior to the start of manufacturing for that applicable Batch. For Lonza to initiate manufacturing of a Batch on the same day that Lonza receives the Starting Material for that Batch, Lonza must receive the applicable Starting Material by no later than [***]. If Starting Material is received later than [***], Lonza will make Commercially Reasonable Efforts, but is not otherwise obligated, to initiate [***]. For clarification, Starting Material received later than [***] will be [***].

c.Shutdowns: The slots will be scheduled in a cGMP suite based on Lonza's twice-yearly mandatory suite shutdowns for suite maintenance. Lonza shall notify the Client of the month in which a shutdown is expected to take place at least [***] in advance and will provide a minimum of [***] advance written notice to Client regarding actual suite shutdown schedule dates ([***]).

d.APS requalification runs will be required as set forth in Section 4.1.3.b of this SOW A-1. If Client requests in writing, Lonza will use Commercially Reasonable Efforts to perform APS requalification runs outside of slots provided pursuant to the Manufacturing Plan, and if Lonza does so Client shall pay the "APS Requalification" fee per run as set forth in the Pricing Table below. Otherwise, Lonza will utilize one (1) manufacturing slot provided pursuant to the Manufacturing Plan for the applicable APS requalification run, and [***].

e.Unless the Parties have executed or are negotiating in good faith a commercial manufacturing agreement with respect to the Product, and subject to SOW A-1 Section 8.a.i below, in the case of a termination by Client pursuant to Section 14.3 of the Agreement, Lonza will perform project closeout activities (example: APSs, equipment movement, etc.) only after completion of all Product manufacturing scheduled during the Term (i.e., the close-out period will commence after expiration of the Term). Lonza will provide a Change Order to Client with the list of closeout activities and associated fees. Such closeout fees are estimated to be [***].

f.Batch release:

a.Notwithstanding anything else to the contrary in SOW A-1, the Agreement, or the Parties' Quality Agreement dated August 25, 2022, Lonza will use Commercially Reasonable Efforts to perform and complete such clinical Batch release, but does not guarantee clinical Batch release, within [***] from the completion of manufacture of that Batch.

2.Section 6 ("Financial Terms") of SOW A-1 is hereby amended by adding the following at the end of the sub-Section titled "Pricing Table":

As of the Amendment 1 Effective Date, the Pricing Table provisions of original SOW A-1 shall be amended by replacing it with the following revised “Amendment 1 Pricing Table”:

Amendment 1 Pricing Table

[***]

[***]

3.Section 6 (“Financial Terms”) of SOW A-1 is hereby further amended by adding the following after the sub-Section titled “Pricing Assumptions” and before the sub-Section titled “Limitation of Liability”:

As of the Amendment 1 Effective Date, the [***] and Pricing Assumptions provisions of original SOW A-1 shall be amended by replacing it with the following revised “Amendment 1 [***]”:

Amendment 1 [***]:

Lonza will invoice the Client on a monthly basis for the following starting with the Amendment 1 Effective Date:

a.APS re-qualification: [***] per run, if applicable. For clarity and confirmation, if Client has not used all its scheduled manufacturing slots, Client may use such slot(s) for APS re-qualification runs at no additional cost and Lonza will accommodate such request.

b.[***]: Pursuant to the Pricing Table above and as otherwise set forth in this SOW A-1 [***] (subject to the terms herein) in an applicable month.

c.Materials: Materials will be invoiced as follows, calculated at [***]:

- [***].

- [***].

d.Starting Material: Invoiced in the month the applicable order is placed by Lonza.

e.Third-Party Testing: Invoiced at [***].

f.Shipping Preparation: Invoiced at [***].

g.Travel: Travel costs incurred by Lonza associated with any project activities (if any) will be invoiced at cost in the month in which such travel costs are incurred. Travel costs may include air fare, hotel accommodations, food, and miscellaneous expenses. All travel costs and expenses will comply with the Client's travel policies and Lonza shall submit all travel arrangements for Client's review prior to booking.

Amendment 1 Pricing Assumptions

a.Any changes made to the manufacturing Process and/or analytical methods that may impact the prices or fees set forth in this SOW A-1 will be covered via Change Order.

b.The [***] include labor and internal testing for each activity in the Project Scope.

c.Price estimate of consumables, raw materials, and other Materials set forth above are only estimates .

d.Materials evaluation, vendor qualification, and additional capital expenditures, if required, are excluded from this SOW A-1 and, if applicable, will be subject to a Change Order or separate agreement.

e.If additional runs or repeated Project Activities are required, additional fees may apply and will be addressed via a Change Order or separate agreement.

f.Shipping pricing listed above will be applicable to the shipping of samples as well as final product using Lonza's standard shipping procedures and shipping containers/material.

- The above shipping quantity is specific to [***] final drug product shipment per batch manufactured. If additional doses are required to be shipped per batch, then the Client and Lonza will mutually agree on a path forward.
- Any Product-specific shipping requirement will lead to revised shipping fees.

g.Project close-out fees are excluded and will be covered via a change order or separate agreement. Such fees are estimated to be approximately [***].

4.Except as modified by this Amendment 1, all other terms and provisions of the Agreement and SOW A-1 shall remain in full force and effect in accordance with their terms.

5.SOW A-1, as amended by this Amendment 1, and the Agreement supersede all other prior agreements, understandings, representations and warranties, oral or written, between the Parties hereto in respect of the subject matter hereof.

6.This Amendment 1 may be executed in any number of counterparts, each of which shall be deemed to be an original and all of which together shall constitute one and the same

document. Each party acknowledges that an original signature or a copy thereof transmitted by facsimile or by pdf shall constitute an original signature for purposes of this Amendment 1.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have executed this Amendment 1 as of the last date of signature below.

Lonza Houston, Inc.	**Arcellx, Inc.**
By:	By:
Name:	Name:
Title:	Title
Date:	Date:

Exhibit 31.1

CERTIFICATION PURSUANT TO

RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,

AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Rami Elghandour, certify that:

1.I have reviewed this Quarterly Report on Form 10-Q of Arcellx, 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 13, 2023

/s/ Rami Elghandour
Rami Elghandour
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO

RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,

AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michelle Gilson, certify that:

1.I have reviewed this Quarterly Report on Form 10-Q of Arcellx, 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 13, 2023

/s/ Michelle Gilson
Michelle Gilson
Chief Financial Officer
(Principal Accounting and Financial Officer)

Exhibit 32.1

ARCELLX, INC.

CERTIFICATION PURSUANT TO

18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Arcellx, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Rami Elghandour, Chief Executive Officer (Principal Executive Officer) of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1)The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: November 13, 2023

/s/ Rami Elghandour
Rami Elghandour
Chief Executive Officer
(Principal Executive Officer)

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Report to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Arcellx, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

ARCELLX, INC.

CERTIFICATION PURSUANT TO

18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Arcellx, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michelle Gilson, Chief Financial Officer (Principal Financial Officer) of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1)The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: November 13, 2023

/s/ Michelle Gilson
Michelle Gilson
Chief Financial Officer
(Principal Financial Officer)

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Report to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Arcellx, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.