UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2024

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: 001-42179

Artiva Biotherapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**83-3614316**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

5505 Morehouse Drive, Suite 100
San Diego CA 92121
(858) 267-4467
(Address including zip code, and telephone number including area code, of registrant's principal executive offices)

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	**ARTV**	**The Nasdaq Global 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 and posted on its corporate web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes ☒ No ☐

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

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 Act). Yes ☐ No ☒

As of October 31, 2024, the registrant had 24,289,328 shares of common stock outstanding.

Artiva Biotherapeutics, Inc.
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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including statements regarding future events, our business strategy, and the plans and objectives of management for future operations, are forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections. In some cases, you can identify forward-looking statements because they contain words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," or "would," or the negative of these words or other similar terms or expressions.

These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- the success, cost, timing and potential indications of our product development activities and clinical trials, including the ongoing clinical trials of AlloNK;
- the timing of our planned Investigational New Drug application (IND) submissions to the United States Food and Drug Administration (FDA) for our product candidates, including AlloNK;
- the timing of the initiation, enrollment and completion of planned clinical trials;
- the ability to obtain regulatory approval for our manufacturing facility in San Diego, California and the cost and timing associated therewith;
- our ability to obtain and maintain regulatory approval of our product candidates, including AlloNK, in any of the indications for which we plan to develop them, and any related restrictions, limitations and/or warnings in the label of an approved product candidate;
- our ability to obtain funding for our operations, including funding necessary to complete the clinical trials of any of our product candidates, including AlloNK;
- our plans to research and develop our product candidates, including AlloNK;
- our ability to attract and retain collaborators with development, regulatory and commercialization expertise;
- the size of the markets for our product candidates, and our ability to serve those markets;
- our ability to successfully commercialize our product candidates, including AlloNK;
- the rate and degree of market acceptance of our product candidates, including AlloNK;
- our ability to develop and maintain sales and marketing capabilities, whether alone or with potential future collaborators;
- the performance of our third-party suppliers and manufacturers;
- the success of competing therapies that are or become available;
- existing regulations and regulatory developments in the United States and other jurisdictions;
- the implementation of our business model and strategic plans for our business and operations;
- our ability to attract and retain key scientific or management personnel;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- our expectations regarding the impact of global health pandemics, geopolitical conflicts and economic uncertainty, including rising interest rates and inflation on our business and operations, including clinical trials, collaborators, contract research organizations (CROs) and employees;
- our expectations regarding the period during which we will qualify as an emerging growth company under the Jumpstart Our Business Startups Act (JOBS Act); and
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates and our ability to operate our business without infringing on the intellectual property rights of others.

These forward-looking statements reflect our management's beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this Quarterly Report on Form 10-Q and are subject to risks and uncertainties. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report on Form 10-Q, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements. We discuss many of the risks associated with the forward-looking statements in greater detail under the heading "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we undertake no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in any forward-looking statements, whether as a result of new information, future events or otherwise.

We may use our website as a means of disclosing material non-public information and for complying with our disclosure obligations under Regulation Fair Disclosure promulgated by the U.S. Securities and Exchange Commission. These disclosures will be included on our website under the "Investors" section.

Part I - Financial Information

Item 1. Financial Statements

ARTIVA BIOTHERAPEUTICS, INC.
Condensed Balance Sheets
(Unaudited)
(in thousands, except share and par value data)

	AS OF	
	SEPTEMBER 30, 2024	DECEMBER 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 55,881	$ 53,504
Short-term investments	90,750	23,467
Accounts receivable (including related party amounts of $569 and $569, respectively)	569	1,034
Other receivables (including related party amounts of $14 and $607, respectively)	132	724
Prepaid expenses and other current assets	3,233	1,092
Total current assets	150,565	79,821
Restricted cash	258	258
Property and equipment, net	6,857	8,096
Operating lease right-of-use assets	14,376	16,547
Financing lease right-of-use asset	276	—
Long-term investments	52,966	—
Other long-term assets	298	392
Total assets	$ 225,596	$ 105,114
Liabilities, convertible preferred stock, and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable (including related party amounts of $304 and $199, respectively)	$ 1,215	$ 614
Accrued expenses (including related party amounts of $1,307 and $2,161, respectively)	8,344	8,017
Current portion of operating lease liabilities	3,614	3,596
Current portion of financing lease liability	119	—
Total current liabilities	13,292	12,227
Operating lease liabilities, net of current portion	11,160	13,316
Financing lease liability, net of current portion	75	—
Simple agreements for future equity ("SAFEs") (including related party amounts of $0 and $20,315, respectively)	—	25,100
Other non-current liabilities	73	73
Total liabilities	24,600	50,716
Commitments and contingencies (Note 11)		
Series A convertible preferred stock, $0.0001 par value; zero and 16,110,463 shares authorized as of September 30, 2024 and December 31, 2023, respectively; zero and 3,673,148 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively; zero and $80,552 aggregate liquidation preference at September 30, 2024 and December 31, 2023, respectively	—	96,767
Series B convertible preferred stock, $0.0001 par value; zero and 10,909,091 shares authorized as of September 30, 2024 and December 31, 2023, respectively; zero and 2,487,237 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively; zero and $120,000 aggregate liquidation preference at September 30, 2024 and December 31, 2023, respectively	—	119,646
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; 10,000,000 and zero shares authorized at September 30, 2024 and December 31, 2023 respectively; zero shares issued and outstanding as of September 30, 2024 and December 31, 2023	—	—
Common stock, $0.0001 par value; 700,000,000 and 38,998,588 shares authorized at September 30, 2024 and December 31, 2023, respectively; 24,287,144 and 809,758 shares issued and outstanding at September 30, 2024 and December 31, 2023	3	—
Additional paid-in capital	431,244	18,988
Accumulated other comprehensive income	338	308
Accumulated deficit	(230,589)	(181,311)
Total stockholders' equity (deficit)	200,996	(162,015)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 225,596	$ 105,114

See accompanying notes to condensed financial statements

ARTIVA BIOTHERAPEUTICS, INC.

Condensed Statements of Operations and Comprehensive Income (Loss)
(Unaudited)
(in thousands, except share and per share data)

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2024	2023	2024	2023
Revenue:				
Collaboration revenue	$ —	$ 26,656	$ —	$ 31,142
License and development support revenue (including related party amounts of $0, $0, $251 and $0, respectively)	—	—	251	—
Total revenue	—	26,656	251	31,142
Operating expenses:				
Research and development (including related party amounts of $1,342, $1,525, $2,802 and $3,335, respectively)	13,524	13,065	37,011	39,098
General and administrative	4,811	2,780	12,255	10,745
Total operating expenses	18,335	15,845	49,266	49,843
Income (loss) from operations	(18,335)	10,811	(49,015)	(18,701)
Other income (expense), net:				
Interest income	1,846	418	3,172	1,952
Change in fair value of SAFEs (including related party amounts of $799, $0, $2,911 and $0, respectively)	(977)	—	(3,597)	—
Other income (expense), net	(6)	50	162	27
Total other income (expense), net	863	468	(263)	1,979
Net income (loss)	$ (17,472)	$ 11,279	$ (49,278)	$ (16,722)
Net income (loss) per share:				
Basic	$ (0.92)	$ 13.98	$ (7.16)	$ (20.89)
Diluted	$ (0.92)	$ 1.62	$ (7.16)	$ (20.89)
Weighted-average common shares outstanding:				
Basic	18,896,829	806,714	6,883,271	800,541
Diluted	18,896,829	6,967,099	6,883,271	800,541
Comprehensive income (loss):				
Net income (loss)	$ (17,472)	$ 11,279	$ (49,278)	$ (16,722)
Other comprehensive income:				
Unrealized gain on investments	217	144	30	271
Comprehensive income (loss)	$ (17,255)	$ 11,423	$ (49,248)	$ (16,451)

See accompanying notes to condensed financial statements

ARTIVA BIOTHERAPEUTICS, INC.

Condensed Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(Unaudited)
(in thousands, except share data)

	SERIES A CONVERTIBLE PREFERRED STOCK		SERIES B CONVERTIBLE PREFERRED STOCK		COMMON STOCK					
	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT	ADDITIONAL PAID-IN CAPITAL	ACCUMULATED OTHER COMPREHENSIVE INCOME	ACCUMULATED DEFICIT	TOTAL STOCKHOLDERS' EQUITY (DEFICIT)
Balance at December 31, 2022	**3,673,148**	**$ 96,767**	**2,487,237**	**$ 119,646**	**792,991**	**$ —**	**$ 11,895**	**$ —**	**$ (152,591)**	**$ (140,696)**
Vesting of shares of common stock subject to repurchase, including early exercise	—	—	—	—	1,425	—	7		—	7
Stock-based compensation expense	—	—	—	—	—	—	1,832	—	—	1,832
Net loss	—	—	—	—	—	—	—	—	(16,717)	(16,717)
Balance at March 31, 2023	**3,673,148**	**$ 96,767**	**2,487,237**	**$ 119,646**	**794,416**	**$ —**	**$ 13,734**	**$ —**	**$ (169,308)**	**$ (155,574)**
Exercise of stock options	—	—	—	—	1,948	—	10	—	—	10
Vesting of shares of common stock subject to repurchase, including early exercise	—	—	—	—	8,835	—	8		—	8
Stock-based compensation expense	—	—	—	—	—	—	2,458	—	—	2,458
Unrealized gain on investments	—	—	—	—	—	—	—	127	—	127
Net loss	—	—	—	—	—	—	—	—	(11,284)	(11,284)
Balance at June 30, 2023	**3,673,148**	**$ 96,767**	**2,487,237**	**$ 119,646**	**805,199**	**$ —**	**$ 16,210**	**$ 127**	**$ (180,592)**	**$ (164,255)**
Vesting of shares of common stock subject to repurchase, including early exercise	—	—	—	—	3,135	—	7	—	—	7
Stock-based compensation expense	—	—	—	—	—	—	1,371	—	—	1,371
Unrealized gain on investments	—	—	—	—	—	—	—	144	—	144
Net income	—	—	—	—	—	—	—	—	11,279	11,279
Balance at September 30, 2023	**3,673,148**	**$ 96,767**	**2,487,237**	**$ 119,646**	**808,334**	**$ —**	**$ 17,588**	**$ 271**	**$ (169,313)**	**$ (151,454)**
Balance at December 31, 2023	**3,673,148**	**$ 96,767**	**2,487,237**	**$ 119,646**	**809,758**	**$ —**	**$ 18,988**	**$ 308**	**$ (181,311)**	**$ (162,015)**
Stock-based compensation expense investments	—	—	—	—	—	—	1,406	—	—	1,406
Unrealized loss on investments	—	—	—	—	—	—	—	(101)	—	(101)
Net loss	—	—	—	—	—	—	—	—	(13,963)	(13,963)
Balance at March 31, 2024	**3,673,148**	**$ 96,767**	**2,487,237**	**$ 119,646**	**809,758**	**$ —**	**$ 20,394**	**$ 207**	**$ (195,274)**	**$ (174,673)**
Exercise of stock options	—	—	—	—	4,444	—	22	—	—	22
Stock-based compensation expense	—	—	—	—	—	—	1,483	—	—	1,483
Unrealized loss on investments	—	—	—	—	—	—	—	(86)	—	(86)
Net loss	—	—	—	—	—	—	—	—	(17,843)	(17,843)
Balance at June 30, 2024	**3,673,148**	**$ 96,767**	**2,487,237**	**$ 119,646**	**814,202**	**$ —**	**$ 21,899**	**$ 121**	**$ (213,117)**	**$ (191,097)**
Conversion of preferred stock into common stock upon completion of initial public offering (IPO)	(3,673,148)	(96,767)	(2,487,237)	(119,646)	6,160,385	1	216,412			216,413
Exercise of stock options	—	—	—	—	1,139	—	6	—	—	6
Issuance of common shares in connection with IPO, net of offering costs	—	—	—	—	14,920,000	2	162,323	—	—	162,325
Issuance of common shares upon the conversion of SAFE notes	—	—	—	—	2,391,418	—	28,697	—	—	28,697
Stock-based compensation expense	—	—	—	—	—	—	1,907	—	—	1,907
Unrealized gain on investments	—	—	—	—	—	—	—	217	—	217
Net loss	—	—	—	—	—	—	—	—	(17,472)	(17,472)
Balance at September 30, 2024	**—**	**$ —**	**—**	**$ —**	**24,287,144**	**$ 3**	**$ 431,244**	**$ 338**	**$ (230,589)**	**$ 200,996**

See accompanying notes to condensed financial statements

ARTIVA BIOTHERAPEUTICS, INC.

Condensed Statements of Cash Flows
(Unaudited)
(in thousands)

	NINE MONTHS ENDED SEPTEMBER 30,	
	2024	**2023**
Operating activities:		
Net loss	$ (49,278)	$ (16,722)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	1,817	1,672
Stock-based compensation	4,796	5,661
Change in fair value of SAFEs (including related party amounts of $2,911 and $0, respectively)	3,597	—
Accretion of discounts and amortization of premiums on investments, net	(1,300)	(173)
Changes in operating assets and liabilities:		
Accounts receivable	465	(1,612)
Other receivables (including related party amounts of $(593) and $(1,040), respectively)	592	(1,338)
Prepaid expenses and other current assets	(2,141)	298
Other long-term assets	94	94
Accounts payable (including related party amounts of $104 and $678, respectively)	601	1,514
Accrued expenses (including related party amounts of $(854) and $345, respectively)	333	(1,055)
Operating lease right-of-use asset and lease liabilities	42	117
Deferred revenue	—	(25,211)
Net cash used in operating activities	(40,382)	(36,755)
Investing activities:		
Purchases of property and equipment	(578)	(2,622)
Purchases of investments	(161,319)	(34,685)
Maturities of investments	42,400	14,000
Net cash used in investing activities	(119,497)	(23,307)
Financing activities:		
Proceeds from issuance of common stock, net of commissions	166,507	—
Proceeds from issuance of simple agreements for future equity	—	23,431
Proceeds from exercise of stock options	28	10
Payments on finance leases	(116)	—
Cash paid in connection with IPO offering costs	(4,163)	—
Repurchase of restricted stock	—	(12)
Net cash provided by financing activities	162,256	23,429
Net increase (decrease) in cash, cash equivalents and restricted cash	2,377	(36,633)
Cash, cash equivalents and restricted cash at beginning of period	53,762	102,776
Cash, cash equivalents and restricted cash at end of period	$ 56,139	$ 66,143
Reconciliation of cash, cash equivalents and restricted cash to the balance sheet:		
Cash and cash equivalents	$ 55,881	$ 65,885
Restricted cash	258	258
Total cash, cash equivalents and restricted cash	$ 56,139	$ 66,143
Supplemental disclosures of noncash activities:		
Property and equipment purchases in accounts payable and accrued liabilities	$ 10	$ 617
Deferred offering costs in accounts payable and accrued liabilities	$ 19	$ —
Conversion of SAFE notes to common stock	$ 28,697	$ —
Conversion of preferred stock to common stock	$ 216,413	$ —
Non-cash additions to financing leases	$ 241	$ —

See accompanying notes to condensed financial statements

NOTES TO CONDENSED FINANCIAL STATEMENTS

(Unaudited)

1. Organization, Liquidity and Basis of Presentation

Organization

Artiva Biotherapeutics, Inc. (the "Company") was incorporated in the State of Delaware on February 14, 2019. The Company is a biopharmaceutical company focused on developing off-the shelf, allogeneic, natural killer ("NK") cell-based therapies that are effective, safe and accessible for patients with devastating autoimmune diseases and cancers.

From its inception to September 30, 2024, the Company has devoted substantially all of its resources to organizing and staffing the Company, business planning, raising capital, establishing and engaging in collaborations, performing research and development, advancing and scaling up product candidate manufacturing, establishing cold chain delivery logistics, establishing and protecting its intellectual property portfolio, and providing general and administrative support for these activities.

Reverse Stock Split

On July 12, 2024, the Company effected a 1-for-4.386 reverse stock split of its common stock and convertible preferred stock. The par value and the authorized shares of the common stock and convertible preferred stock were not adjusted as a result of the reverse stock split. These accompanying condensed financial statements and notes to the condensed financial statements give retroactive effect to the reverse stock split for all periods presented.

Initial Public Offering

On July 22, 2024, the Company completed its Initial Public Offering (the "IPO"), pursuant to which it issued and sold 13,920,000 shares of common stock at a public offering price of $12.00 per share. The aggregate gross proceeds of the IPO were $167.0 million before underwriter discounts and commissions, fees, and expenses of $15.9 million, for net proceeds from the IPO of $151.1 million. On July 25, 2024, the underwriters partially exercised their 30-day option and purchased an additional 1,000,000 shares of the Company's common stock at the IPO price, upon which the Company received additional gross proceeds of $12.0 million before commissions of $0.8 million, for net proceeds of approximately $11.2 million. The aggregate net proceeds of the IPO was $162.3 million (the "IPO Proceeds"). All underwriter discounts and commissions, fees, and expenses, including deferred offering costs have been charged to additional paid in capital as recorded against the gross proceeds.

Liquidity

The Company has incurred net losses and negative cash flows from operations since inception, has a significant accumulated deficit and expects to continue to incur net losses for the foreseeable future. The Company has never generated any revenue from product sales and does not expect to generate any revenues from product sales unless and until it successfully completes development of and obtains regulatory approval for its product candidates, which will not be for several years, if ever. The Company has an accumulated deficit of $230.6 million as of September 30, 2024. During the nine months ended September 30, 2024, the Company used $40.4 million of cash for operating activities. As of September 30, 2024, the Company has $199.6 million in cash, cash equivalents and investments. From inception through September 30, 2024, the Company has raised aggregate gross proceeds of $401.4 million to fund operations, comprised primarily from proceeds received from the IPO, including proceeds from the underwriters partial exercise of their purchase option, issuances of convertible promissory notes, simple agreements for future equity ("SAFEs") and private placements of convertible preferred stock. Since inception through September 30, 2024, the Company has also received $39.9 million in upfront and reimbursable research service payments from Merck Sharp & Dohme Corp. ("Merck"). Management estimates that there is no substantial doubt about the Company's ability to continue as a going concern for the one year period following the date that these unaudited condensed financial statements and accompanying notes were issued, as the Company's existing cash, cash equivalents and investments will be sufficient to fund planned operations at least through the end of 2026. As such, the prior substantial doubt about the Company's ability to continue as a going concern as discussed in the Company's December 31, 2023 audited financial statements as included in the Company's prospectus dated July 18, 2024 related to its IPO filed pursuant to Rule 424(b)(4) under the Securities Act of 1933, no longer exists.

If the Company is unable to obtain additional funding before achieving sufficient profitability and positive cash flows from operations, if ever, the Company will be forced to delay, reduce or eliminate some or all of its research and development programs, which could adversely affect its business prospects, or the Company may be unable to continue operations. Although management continues to pursue plans to obtain additional funding before achieving sufficient profitability and positive cash flows from operations, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all.

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") and pursuant to rules and regulations of the Securities Exchange Commission for interim financial information. Accordingly, they do not include all of the information and notes required by GAAP for complete financial statements. These unaudited condensed financial statements include only normal and recurring adjustments that the Company believes are necessary to fairly state the Company's financial position and the results of its operations and cash flows. The results for the three and nine months ended September 30, 2024 and 2023 are not necessarily indicative of the results expected for the full fiscal year or any subsequent interim period. The unaudited condensed balance sheet as of September 30, 2024 has been derived from the financial statements as of that date but does not include all disclosures required by GAAP for complete financial statements. As all of the disclosures required by GAAP for complete financial statements are not included herein, these condensed financial statements and the notes accompanying herein should be read in conjunction with the Company's audited financial statements as of and for the year ended December 31, 2023 included in the Company's prospectus dated July 18, 2024 related to its IPO filed pursuant to Rule 424(b)(4) under the Securities Act of 1933. Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") promulgated by the Financial Accounting Standards Board ("FASB").

2. Summary of Significant Accounting Policies

The Company's significant accounting policies are disclosed in the audited financial statements as of and for the year ended December 31, 2023, included in the Company's prospectus dated July 18, 2024 related to its IPO filed pursuant to Rule 424(b)(4) under the Securities Act of 1933. Since the date of those financial statements, there have been no changes to its significant accounting policies, except where noted below.

Use of Estimates

The preparation of condensed 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 condensed financial statements and the reported amounts of expenses during the reporting period. Accounting estimates and management judgments reflected in the condensed financial statements include: revenue recognized, the accrual of research and development expenses, common stock, stock-based compensation, SAFEs and operating lease liabilities. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may materially differ from these estimates and assumptions.

Investments

The Company holds investments in commercial paper, government and government agency bonds, and corporate bonds. The Company has classified its investment securities as current and non-current assets on the condensed balance sheets based on each security's contractual maturity date, and all investment securities are accounted for as available-for-sale because these investment securities are considered available for use in operations. The Company carries these securities at fair value and reports unrealized gains and losses as a separate component of accumulated other comprehensive income. The cost of debt securities is adjusted for amortization of purchase premiums and accretion of discounts to maturity. Such amortization and accretion are included in other income in the condensed statements of operations and comprehensive income (loss). Realized gains and losses on sales of securities are determined using the specific identification method and recorded in other income in the condensed statements of operations and comprehensive income (loss).

As of September 30, 2024, and December 31, 2023, accrued interest receivables on investments were $0.7 million and $0.1 million, respectively, and are included in prepaid expenses and other current assets in the condensed balance sheets. The Company does not measure an allowance for credit losses for accrued interest receivables. For the purposes of identifying and measuring an impairment, accrued interest is excluded from both the fair value and amortized cost basis of the investment. Uncollectible accrued interest receivables associated with an impaired debt security are reversed against interest income upon identification of the impairment. No accrued interest receivables were written off during the three and nine months ended September 30, 2024 and 2023.

Restricted Cash

Restricted cash is comprised of cash that is restricted as to withdrawal or use under the terms of certain contractual agreements. Restricted cash as of September 30, 2024 and December 31, 2023, was $0.3 million consisting of collateral for letters of credit related to the Company's lease agreements and is included in non-current assets in the condensed balance sheets (see Note 11).

Net Income (Loss) Per Share

Basic net income (loss) per share is calculated by dividing the net income (loss) by the weighted-average number of common shares outstanding for the period. Diluted net income (loss) per share is computed by dividing the net income (loss) by the weighted-average number of shares of common stock and common stock equivalents outstanding for the period. Common stock equivalents are only included when their effect is dilutive. The Company's potentially dilutive securities include shares of its convertible preferred stock, as well as outstanding stock options and restricted stock units under the Company's equity incentive plan and have been excluded from the computation of diluted net loss per share, for all periods except the three months ended September 30, 2023, as they would be anti-dilutive to the net loss per share.

The Company recorded net income for the three months ended September 30, 2023. The Company used the treasury stock method and if-converted method to determine the weighted-average number of shares of common stock equivalents outstanding for the three months ended September 30, 2023. The following table sets forth the computation of basic and diluted net income (loss) per share (in thousands, except share and per share data):

	THREE MONTHS ENDED		NINE MONTHS ENDED	
	SEPTEMBER 30, 2024	SEPTEMBER 30, 2023	SEPTEMBER 30, 2024	SEPTEMBER 30, 2023
Basic Net Income (Loss) per share				
Net income (loss)	$ (17,472)	$ 11,279	$ (49,278)	$ (16,722)
Weighted average common shares outstanding - basic	18,896,829	806,714	6,883,271	800,541
Net income (loss) per share - basic	$ (0.92)	$ 13.98	$ (7.16)	$ (20.89)
Diluted Net Income (Loss) per share				
Net income (loss)	$ (17,472)	$ 11,279	$ (49,278)	$ (16,722)
Weighted average common shares outstanding - basic	18,896,829	806,714	6,883,271	800,541
Weighted average effect of dilutive securities:				
Series A preferred stock	—	3,673,148	—	—
Series B preferred stock	—	2,487,237	—	—
Weighted average common shares outstanding - diluted	18,896,829	6,967,099	6,883,271	800,541
Net income (loss) per share - diluted	$ (0.92)	$ 1.62	$ (7.16)	$ (20.89)

The following table sets forth the outstanding potentially dilutive securities that have been excluded in the calculation of diluted net loss per share because their inclusion would be anti-dilutive for the nine months ended September 30, 2024 and 2023:

	AS OF SEPTEMBER 30, 2024	AS OF SEPTEMBER 30, 2023
Convertible preferred stock	—	6,160,385
Unvested restricted stock units	533,484	22,514
Options to purchase common stock	2,238,816	1,323,348
Total	2,772,300	7,506,247

Recently Adopted Accounting Standards

In August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity ("ASU 2020-06")*. ASU 2020-06 was issued to reduce the complexity associated with accounting for certain financial instruments with characteristics of liabilities and equity. ASU 2020-06 reduces the number of accounting models for convertible debt instruments and redeemable convertible preferred stock and improves the disclosures for convertible instruments and related earnings per share guidance. ASU 2020-06 also amends the guidance for the derivatives scope exception for contracts in an entity's own equity and improves and amends the related earnings per share guidance. For public entities that qualify as a filer with the Securities and Exchange Commission, excluding entities eligible to be smaller reporting companies, ASU 2020-06 is effective for fiscal annual periods beginning after December 15, 2021, including interim periods within those fiscal years. For nonpublic entities, ASU 2020-06 is effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods within those

fiscal years. ASU 2020-06 must be adopted as of the beginning of a Company's annual fiscal year. The Company adopted this standard on January 1, 2024, and the adoption of the standard did not have a material impact on its financial statements.

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting—Improvements to Reportable Segment Disclosures* ("ASU 2023-07"). The update requires entities to disclose their significant segment expense categories and amounts for each reportable segment. Significance is assessed using both quantitative and qualitative factors depending on the facts and circumstances. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023, and interim periods in fiscal years beginning after December 15, 2024. The Company is currently evaluating the impact that this standard will have on the related disclosures in its financial statements.

In December 2023, the FASB issued ASU 2023-09, *Improvements to Income Tax Disclosures* ("ASU 2023-09"). The update requires enhanced disclosures on income taxes paid, adds disaggregation of continuing operations before income taxes between foreign and domestic earnings and defines specific categories for the reconciliation of jurisdictional tax rate to effective tax rate. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024, and can be applied on a prospective basis. The Company is currently evaluating the impact that this standard will have on the related disclosures in its financial statements.

3. Fair Value Measurements

The following table presents information about the Company's financial assets and liabilities that are measured at fair value on a recurring basis and indicates their respective levels within the fair value hierarchy (in thousands):

		AS OF SEPTEMBER 30, 2024			
	CLASSIFICATION	TOTAL	LEVEL 1	LEVEL 2	LEVEL 3
Assets					
Money market funds	Cash and cash equivalents	$ 35,353	$ 35,353	$ —	$ —
Commercial paper	Cash and cash equivalents	11,495	—	11,495	—
Government bonds	Cash and cash equivalents	6,281	—	6,281	—
Commercial paper	Short-term investments	73,180	—	73,180	—
Government agency bonds	Short-term investments	4,505	—	4,505	—
Corporate bonds	Short-term investments	13,065	—	13,065	—
Government and government agency bonds	Long-term investments	45,142	—	45,142	—
Corporate bonds	Long-term investments	7,824	—	7,824	—
Total assets		$ 196,845	$ 35,353	$ 161,492	$ —

		AS OF DECEMBER 31, 2023			
	CLASSIFICATION	TOTAL	LEVEL 1	LEVEL 2	LEVEL 3
Assets					
Money market funds	Cash and cash equivalents	$ 28,517	$ 28,517	$ —	$ —
Commercial paper	Short-term investments	2,090	—	2,090	—
Government and government agency bonds	Short-term investments	19,982	—	19,982	—
Corporate bonds	Short-term investments	1,395	—	1,395	—
Total assets		$ 51,984	$ 28,517	$ 23,467	$ —
Liabilities					
SAFEs	Liabilities	$ 25,100	$ —	$ —	$ 25,100
Total liabilities		$ 25,100	$ —	$ —	$ 25,100

The carrying amounts of all cash and cash equivalents, accounts receivable, other receivable, prepaid and other current assets, accounts payable, and accrued expenses are considered to be representative of their respective fair values because of the short-term nature of those instruments.

Short-Term and Long-Term Investments

The Company's assets with a fair value categorized as Level 2 within the fair value hierarchy consist of commercial paper, government and government agency bonds, and corporate bonds. These assets have been initially valued at the transaction price and subsequently valued at the end of each reporting period utilizing third-party pricing services. The pricing services utilize industry standard valuation models whereby all significant inputs, including benchmark yields, reported trades, broker/dealer quotes, issuer spreads, bids, offers, or other market-related data, are observable.

Simple Agreements for Future Equity

The estimated fair value of the SAFEs (see Note 7) is determined based on the aggregated, probability-weighted average of the outcomes of certain scenarios, including: (i) equity financing, with conversion of the SAFEs into a number of shares of convertible preferred stock at the lower of the post-money valuation cap price of $48.25 and the discount price (the lowest price of the standard convertible preferred stock sold in the equity financing multiplied by the specified discount rate of 85%); (ii) liquidity event (change of control, direct listing, or an initial public offering,) with mandatory conversion to common stock at the lower of post-money valuation cap price of $48.25 and discount price (price of the common stock multiplied by the discount rate of 85%); and (iii) dissolution event, with SAFE holders automatically entitled to receive cash payments equal to the purchase amount, prior to and in preference to any distribution of any assets or surplus funds to the holders of convertible preferred and common stock. On May 29, 2024, the Company executed an amendment to the SAFEs (the "SAFE Amendment"). The SAFE Amendment amended the definition of liquidity event to exclude an initial public offering and amended the definition of the discount price under an initial public offering to the lower of (a) the price per share of common stock sold to the public by the underwriters in the initial public offering multiplied by the discount rate of 85% or (b) the post-money valuation cap price of $48.25. The combined value of the probability-weighted average of those outcomes is then discounted back to each reporting period in which the SAFEs are outstanding, in each case based on a risk-adjusted discount rate estimated based on the implied interest rate using the changes in observed interest rates of corporate debt that the Company believes is appropriate for those probability-adjusted cash flows.

Fair value measurements associated with SAFEs were determined based on significant inputs not observable in the market, which represent Level 3 measurements within the fair value hierarchy. Increases and decreases in the fair value of the SAFEs can result from updates to assumptions such as expected timing and probability of a qualified financing event, or changes in discount rates, among other assumptions. Based on management's assessment of the valuation of the SAFEs, performed by the Company's third-party valuation specialists, none of the changes in the fair value of those instruments were due to changes in the Company's own credit risk for the reporting periods presented. Judgement is used in determining these assumptions as of the initial valuation date and at each subsequent reporting period. Changes or updates to assumptions could have a material impact on the reported fair value, and the change in fair value of SAFEs and the results of operations in any given period.

In connection with the closing of the IPO, the Company's outstanding convertible SAFE shares automatically converted into 2,391,418 shares of common stock.

The following tables summarize the significant inputs not observable in the market upon which the fair value measurements associated with the SAFEs were determined:

	VALUATION TECHNIQUE	UNOBSERVABLE INPUT	AS OF DECEMBER 31, 2023
Liabilities			
SAFEs	Scenario-based approach	Probability weighting	15.0% - 70.0%
		Discount rate	20.1%
		Remaining term to event (in years)	0.50 - 0.75

The following table summarizes the changes in fair value associated with Level 3 financial instruments held during the periods presented (in thousands):

	SAFEs
Balance at December 31, 2023	$ 25,100
Changes in fair value of SAFEs	3,597
Conversion of SAFEs to common stock	(28,697)
Balance at September 30, 2024	$ —

4. Cash, Cash Equivalents and Investments

It is the Company's policy to mitigate credit risk in its financial assets by maintaining a well-diversified portfolio that limits the amount of exposure as to maturity and investment type.

The following table summarizes the Company's cash and cash equivalents, short-term investments, and long-term investments for each of the periods presented (in thousands):

			AS OF SEPTEMBER 30, 2024			
	CLASSIFICATION	MATURITY	AMORTIZED COST	GROSS UNREALIZED GAINS	GROSS UNREALIZED LOSSES	FAIR MARKET VALUE
Cash and money market funds	Cash and cash equivalents	Less than three months	$ 38,105	$ —	$ —	$ 38,105
Commercial paper	Cash and cash equivalents	Less than three months	11,493	2	—	11,495
Government bonds	Cash and cash equivalents	Less than three months	6,258	23	—	6,281
Commercial paper	Short-term investments	1 year or less	73,098	82	—	73,180
Government agency bonds	Short-term investments	1 year or less	4,497	8	—	4,505
Corporate bonds	Short-term investments	1 year or less	13,042	23	—	13,065
Government and government agency bonds	Long-term investments	Greater than 1 year	44,955	187	—	45,142
Corporate bonds	Long-term investments	Greater than 1 year	7,811	13	—	7,824
Total cash and cash equivalents, short-term investments, and long-term investments			$ 199,259	$ 338	$ —	$ 199,597

			AS OF DECEMBER 31, 2023			
	CLASSIFICATION	MATURITY	AMORTIZED COST	GROSS UNREALIZED GAINS	GROSS UNREALIZED LOSSES	FAIR MARKET VALUE
Cash and money market funds	Cash and cash equivalents	Less than three months	$ 53,504	$ —	$ —	$ 53,504
Commercial paper	Short-term investments	1 year or less	2,048	42	—	2,090
Government and government agency bonds	Short-term investments	1 year or less	19,728	254	—	19,982
Corporate bonds	Short-term investments	1 year or less	1,383	12	—	1,395
Total cash, cash equivalents and short-term investments			$ 76,663	$ 308	$ —	$ 76,971

As of September 30, 2024, the Company did not have any investments with gross unrealized losses. The Company does not intend to sell the investments and it is not more likely than not that the Company will be required to sell the investments before recovery of their amortized cost basis. As of September 30, 2024, no allowance for credit losses was recorded.

5. Property and Equipment, Net

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

	AS OF	
	SEPTEMBER 30, 2024	DECEMBER 31, 2023
Lab equipment	$ 10,284	$ 9,760
Furniture and fixtures	872	871
Computers and software	616	607
Leasehold improvements	410	390
	12,182	11,628
Less accumulated depreciation	(5,325)	(3,532)
Total property and equipment, net	$ 6,857	$ 8,096

The Company recognized $0.6 million and $1.8 million in depreciation expense for the three and nine months ended September 30, 2024, respectively, and $0.6 million and $1.7 million in depreciation expense for the three and nine months ended September 30, 2023, respectively.

6. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	AS OF	
	SEPTEMBER 30, 2024	DECEMBER 31, 2023
Accrued research and development expenses	$ 2,218	$ 2,861
Accrued payroll and other employee benefits	4,806	4,047
Other accrued expenses	1,320	1,109
Total accrued expenses	$ 8,344	$ 8,017

7. Simple Agreement for Future Equity

During 2023, the Company entered into SAFEs with various existing investors and related parties with aggregate gross proceeds of $24.4 million. The SAFEs granted investors with rights to participate in a future equity financing. The SAFEs have no maturity dates and bear no interest. Upon an equity financing, the SAFEs will automatically convert into the type of stock issued in the financing at a per share conversion price equal to the greater of (i) the purchase amount of the SAFEs divided by the post-money valuation cap price of $48.25 per share, or (ii) the purchase amount of the SAFEs divided by the 85% per share price paid by investors in the financing. Upon an initial public offering, the SAFEs will automatically convert into shares of common stock equal to the purchase amount of the SAFE divided by the discount price (the lower of (a) the price per share of common stock sold to the public by the underwriters in the initial public offering multiplied by the discount rate of 85% or (b) the post-money valuation cap price of $48.25 per share). Other conversion events include liquidity events (a change of control or direct listing). Upon a liquidity event, each investor will automatically be entitled to receive a portion of proceeds equal to the greater of (i) the purchase amounts of the SAFEs, or (ii) the amount payable in the number of common shares equal to the purchase amount of the SAFEs divided by the 85% per share price. Upon a dissolution event and to the extent sufficient funds are available, the holders of SAFEs shall be entitled to receive cash payments equal to the purchase amount, prior to and in preference to any distribution of any assets or surplus funds to the holders of convertible preferred and common stock.

In connection with the closing of the IPO, the Company's outstanding convertible SAFE shares automatically converted into 2,391,418 shares of common stock.

8. Collaboration and License Agreements

The Company has entered into several agreements with GC Cell and related entities concerning its NK cell therapy platform and manufacturing of its core products, as described below.

Option and License Agreement with GC Cell

In September 2019, the Company entered into an option and license agreement with GC Cell Corporation ("GC Cell"), formerly Green Cross Cell Corporation, as amended in June 2020 and February 2022 (the "Core Agreement"). Under the Core Agreement, GC Cell granted the Company an exclusive, royalty-bearing license, with the right to sublicense through multiple tiers, under certain intellectual property and technology owned or controlled by GC Cell relating to non-genetically modified and genetically modified NK cells, and culturing, engineering, manufacturing thereof, to research, develop, manufacture, and commercialize NK cell pharmaceutical products in the Artiva Territory, which is anywhere in the world except for Asia, Australia, and New Zealand. GC Cell retained rights under the license to allow it and its affiliates to perform obligations under the Core Agreement and other agreements between the Company and them.

Under the Core Agreement, GC Cell agreed to conduct a discovery, research, preclinical development, and manufacturing program under a plan approved by a Joint Steering Committee (the "JSC"), to generate and identify product candidates for nomination as option candidates. GC Cell will bear all costs for its work under the R&D Plan, except that the Company will bear all costs for completing IND-enabling activities performed by GC Cell on behalf of the Company, other than certain efficacy studies.

For each product candidate determined by the JSC to be an option candidate, the Company has an exclusive option under the Core Agreement to obtain an exclusive, sublicensable license to research, develop, manufacture and commercialize such candidate in the Artiva Territory for any therapeutic, prophylactic or diagnostic uses in humans, on economic terms to be determined in good faith by the parties. GC Cell retains exclusive rights to the licensed technology in Asia, Australia, and New Zealand, though the Company has the right to request, and GC Cell has agreed to consider in good faith, inclusion of Australia, New Zealand, and/or specific countries in Asia in the Artiva Territory on a product-by-product basis. If the Company elects not to exercise the option with respect to a particular option candidate, GC Cell retains the right to continue development of such candidate. As of September 30, 2024, the Company has exercised its rights to license four option candidates, AB-101 (AlloNK), AB-201, AB-202, and AB-205, as described below.

The Company has control over and will bear the costs of the development, regulatory, manufacturing, and commercialization activities relating to the option candidates for which it has exercised its option, each a licensed product. Accordingly, the Company has certain diligence obligations and must use commercially reasonable efforts to develop and seek regulatory approval for each licensed product in at least one indication in the United States and the European Union, and following regulatory approval in a country, to commercialize such licensed product in at least one indication in such country. The Core Agreement provides that the Company has the right to engage GC Cell or its appropriate affiliate to provide research and manufacturing services for the licensed products being developed by the Company in the Artiva Territory under separately executed service agreements.

Under the Core Agreement, the Company is obligated to pay a low single-digit percentage royalty on net sales of any licensed products, the manufacture, use or sale of which is claimed by or uses any Core IP. The royalty rate is subject to reduction under certain scenarios, and royalties are payable on a product-by-product and country-by-country basis, beginning with the first commercial sale of a licensed product and continuing until the later of: (i) expiration of the last-to-expire claim of the licensed patents and jointly owned patents in the country of sale; (ii) expiration of any regulatory exclusivity for a licensed product in that country; and (iii) the tenth anniversary of the first commercial sale of a licensed product in that country. The Company also has the exclusive option to extend its license to the Core IP to be worldwide with respect to products originated from the Company in exchange for a specified increase in the applicable royalty. GC Cell is also obligated to pay the Company a royalty at a rate equal to 50% of the royalty payable by the Company for such product in the Artiva Territory on net sales outside the Artiva Territory of any licensed product, the manufacture, use or sale of which is claimed by or uses any jointly owned intellectual property. As of September 30, 2024, the Company has not recognized any net sales royalties under the Core Agreement.

AB-101 Selected Product License Agreement

In November 2019, the Company entered into a license agreement with GC Cell for its AB-101 product candidate, as amended in February 2022 (the "AB-101 Agreement"). AB-101 is the first product for which the Company exercised its option under the Core Agreement. Under the AB-101 Agreement, GC Cell granted the Company an exclusive, royalty-bearing license in the Artiva Territory, with the right to sublicense through multiple tiers, under certain intellectual property and technology owned or controlled by GC Cell, to research, develop, manufacture, and commercialize AB-101.

Under the AB-101 Agreement, the Company is obligated to pay tiered royalties in the low-mid to high single-digit percentage range on annual net sales of any licensed AB-101 products. The royalty rate is subject to reduction under certain scenarios, and royalties are payable on a product-by-product and country-by-country basis, beginning with the first commercial sale of a licensed AB-101 product and continuing until the later of: (i) expiration of the last-to-expire claim of the licensed patents and jointly owned patents in the country of sale; (ii) expiration of any regulatory exclusivity for a licensed product in that country; and (iii) the tenth anniversary of the first commercial sale of a licensed product in that country. The Company is also obligated to make milestone payments to GC Cell of: (1) up to $22.0 million upon the first achievement of certain development milestones; and (2) up to $55.0 million upon the first achievement of certain sales milestones. GC Cell is also obligated to pay the Company a royalty at a rate equal to 50% of the royalty payable by the Company for such product in the Artiva Territory on net sales outside the Artiva Territory of any licensed AB-101 product, the manufacture, use or sale of which is claimed by or uses any jointly owned intellectual property. As of September 30, 2024, the Company has not recognized any net sales royalties or milestones under the AB-101 Agreement.

AB-201 Selected Product License Agreement

In October 2020, the Company entered into a license agreement with GC Cell for its AB-201 product candidate, as amended in February 2022 (the "AB-201 Agreement"). AB-201 is the second product for which the Company exercised its option under the Core Agreement. Under the AB-201 Agreement, GC Cell granted the Company an exclusive, royalty-bearing license in the Artiva Territory, with the right to sublicense through multiple tiers, under certain intellectual property and technology owned or controlled by GC Cell, to research, develop, manufacture, and commercialize AB-201.

Under the AB-201 Agreement, the Company is obligated to pay tiered royalties in the mid to high single-digit percentage range on annual net sales of any licensed AB-201 products. The royalty rate is subject to reduction under certain scenarios, and royalties are payable on a product-by-product and country-by-country basis, beginning with the first commercial sale of a licensed AB-201 product and continuing until the later of: (i) expiration of the last-to-expire claim of the licensed patents and jointly owned patents in the country of sale; (ii) expiration of any regulatory exclusivity for a licensed product in that country; and (iii) the tenth anniversary of the first commercial sale of a licensed product in that country. The Company is also obligated to make milestone payments to GC Cell of: (1) up to $25.0 million upon the first achievement of certain development milestones; and (2) up to $55.0 million upon the first achievement of certain sales milestones. GC Cell is also obligated to pay the Company a royalty at a rate equal to 50% of the royalty payable by the Company for such product in the Artiva Territory on net sales outside the Artiva Territory of any licensed AB-201 product, the manufacture, use or sale of which is claimed by or uses any jointly owned intellectual property.

In September 2023, the Company entered an amendment to the AB-201 Agreement (the "Amended AB-201 Agreement"). This amendment granted back GC Cell an exclusive, royalty and milestone bearing license to all information and patents controlled by the Company that relate specifically to the research, development, manufacture and use of AB-201, to be used outside of the Artiva Territory. Under the Amended AB-201 Agreement, the Company will receive tiered royalties in the low single-digit percentage range on annual GC Cell net sales of AB-201 outside of the Artiva Territory. The royalties are payable on a product-by-product and country-by-country basis, beginning with the first commercial sale of AB-201 outside of the Artiva Territory and continuing until the later of: (i) expiration of the last-to-expire claim of the licensed patents in the country of sale; (ii) expiration of any regulatory exclusivity for a licensed product in that country; and (iii) the tenth anniversary of the first commercial sale of a licensed product in that country. The Company will also receive milestone payments upon achievement of certain development milestones, totaling $1.8 million. In December 2023, GC Cell achieved the first regulatory milestone under the Amended AB-201 Agreement for first IND acceptance for AB-201 outside the Artiva Territory.

The Company recognized zero and $0.3 million of license and development support-related revenue during the three and nine months ended September 30, 2024, respectively, in the condensed statements of operations and comprehensive income (loss), related to development support activities under the Amended AB-201 Agreement. During the three and nine months ended September 30, 2023, no license and development support-related revenue was recognized. As of September 30, 2024 and December 31, 2023, total accounts receivable related to the Amended AB-201 Agreement were $0.6 million.

AB-205 Selected Product License Agreement

In December 2022, the Company entered into a license agreement with GC Cell for its AB-205 product candidate (the "AB-205 Agreement"). AB-205 is the fourth product for which the Company exercised its option under the Core Agreement. Under the AB-205 Agreement, GC Cell granted the Company an exclusive, royalty-bearing license in the Artiva Territory, with the right to sublicense through multiple tiers, under certain intellectual property and technology owned or controlled by GC Cell, to research, develop, manufacture, and commercialize AB-205.

Under the AB-205 Agreement, the Company is also obligated to pay tiered royalties in the mid to high single-digit percentage range on annual net sales of any licensed AB-205 products. The royalty rate is subject to reduction under certain scenarios, and royalties are payable on a product-by-product and country-by-country basis, beginning with the first commercial sale of a licensed AB-205 product and continuing until the later of: (i) expiration of the last-to-expire claim of the licensed patents and jointly owned patents in the country of sale; (ii) expiration of any regulatory exclusivity for a licensed product in that country; and (iii) the tenth anniversary of the first commercial sale of a licensed product in that country. Upon election by the Company to proceed with clinical development of AB-205 (prior to which the Company may not make, use or sell AB-205 for clinical development purposes), the Company is obligated to pay a one-time payment of $2.5 million to GC Cell. Thereafter, the Company is also obligated to make milestone payments to GC Cell of: (i) up to $29.5 million upon the first achievement of certain development milestones, excluding any payments for the Development Cost Share as defined in the AB-205 Agreement; and (ii) up to $28.0 million upon the first achievement of certain sales milestones. As of September 30, 2024, the Company has not recognized any net sales royalties or milestones under the AB-205 Agreement.

In connection with the AB-205 License Agreement, the Company recognized zero and $0.1 million of expense reimbursements for development costs invoiced to GC Cell for the three and nine months ended September 30, 2024, respectively, and $0.5 million and $1.0 million for the three and nine months ended September 30, 2023, respectively. During the three and nine months ended September 30, 2024, the Company received payments from GC Cell totaling $0.7 million and $1.7 million, respectively. As of September 30, 2024 and December 31, 2023, the Company recorded zero and $0.6 million, respectively, in the condensed balance sheets as other receivable from GC Cell.

Research Services Agreement with GC Cell

As contemplated by the Core Agreement, in August 2020 the Company entered into the GC Cell Research Services Agreement, as amended in February 2022, under which GC Cell agreed to provide research services in support of the research and development of one or more of the products the Company has licensed from GC Cell.

The agreement provides that the parties will agree to specific projects as work orders under the GC Cell Research Services Agreement. Each work order shall set forth, upon terms mutually agreeable to GC Cell and the Company, the specific services to be performed by GC Cell, the timeline and schedule for the performance of the services, and the compensation to be paid by the Company to GC Cell for the provision of such services, as well as any other relevant terms and conditions (see Note 10).

Master Manufacturing Agreement with GC Cell

In March 2020, the Company entered into a Master Agreement for Manufacturing Services (the "Manufacturing Agreement") with GC Cell, under which GC Cell agreed to manufacture specified products under individual work orders for use in the Company's Phase 1 and Phase 2 clinical trials. Each work order will contain an estimated budget of service fees and out-of-pocket costs to be incurred in the performance of services under the agreement and the work order, as well as additional terms and conditions relating to the estimated budget. The Company will own all results and data generated by GC Cell under the Manufacturing Agreement (see Note 10).

Merck Exclusive License and Collaboration Agreement

In January 2021, the Company entered into the Exclusive License and Research Collaboration Agreement (the "Merck Collaboration Agreement") with Merck for the discovery, development, manufacture and commercialization of CAR-NK cells that target certain solid tumor antigens. Merck paid the Company $30.0 million upfront for two target programs under the Merck Collaboration Agreement. As part of the Merck Collaboration Agreement, the Company was also eligible to receive additional payments for achieving certain development, regulatory approval and sales milestones, as well as royalties on net sales. In addition, the Company would be reimbursed for the conduct of each research program, including external research costs and manufacture and supply of clinical material for Phase 1 clinical trials.

Concurrent with entering into the Merck Collaboration Agreement, the Company also entered into an agreement with GC Cell to obtain exclusive, worldwide rights to GC Cell's CAR-NK technology with respect to the licensed products and to engage GC Cell to perform services in support of the research programs ("Partnered Program License Agreement"). The Company agreed to reimburse GC Cell for research and development services as these services were provided. The Company was required to pay GC Cell 100% of regulatory milestones, sales milestones and royalty payments received by Merck relating to products in Asia, Australia and New Zealand and 50% of upfront payments, license fees, regulatory milestones, sales milestones and royalty payments received by Merck relating to products in all other territories.

In October 2023, the Merck Collaboration Agreement and development thereunder was terminated by Merck.

The Company applied ASC 808 to the Merck Collaboration Agreement and determined that the agreements were applicable to such guidance. The Company concluded that Merck represented a customer and applied relevant guidance from ASC 606 to account for the Merck Collaboration Agreement. In accordance with this guidance, the Company identified its performance obligations, including its grant of a license to Merck to certain of its intellectual property subject to certain conditions, transfer of technology, its conduct of research services, and its participation in a joint research committee. The Company determined that its grant of a license to Merck to certain of its intellectual property subject to certain conditions was not distinct from other performance obligations because such grant is dependent on the conduct and results of the research services.

Additionally, the Company determined that its conduct of research services was not distinct from other performance obligations since the research could not be conducted without also delivering the rights to the license, developed intellectual property and technology transfer. Accordingly, the Company determined that all performance obligations should be accounted for as one combined performance obligation for each target program, and that the combined performance obligation is transferred over the expected term of the conduct of the research services, which is collectively estimated to be four years, which represents the combined terms for the research programs ("Expected Research Term").

The Company assessed the upfront, non-refundable and non-creditable payment of $30.0 million received in January 2021 and concluded that there was not a significant financing component to the Merck Collaboration Agreement.

The Company also assessed the effects of the variable consideration under the Merck Collaboration Agreement. Such assessment evaluated, among other things, the likelihood of receiving: (i) various clinical, regulatory and commercial milestone payments; and (ii) royalties on net sales. Based on its assessment, the Company concluded that given the substantial uncertainty related to their achievement, such variable consideration was not included in the transaction price.

In accordance with ASC 606, the Company determined that the initial transaction price under the Merck Collaboration Agreement equaled $58.0 million, consisting of the upfront, non-refundable and non-creditable payment of $30.0 million and the aggregate estimated research and development fees of $28.0 million. The initial transaction price was allocated evenly to each of the two product targets. The upfront payment of $30.0 million was recorded as deferred revenue, and was recognized as revenue over the Expected Research Term as the research services were the primary component of the combined performance obligations. Revenue associated with the upfront payment was recognized based on actual costs incurred as a percentage of the estimated total costs expected to be incurred over the Expected Research.

The Company assessed the payments made to GC Cell in connection with the Partnered Program License Agreement and concluded that all payments received from Merck and paid to GC Cell should be reflected within the Company's condensed financial statements on a gross basis. The Company recognized payments from Merck as collaboration revenue as the performance obligation was satisfied over time, and payments made to GC Cell were recognized as research and development expense, as incurred.

The Company recognized zero revenue under the Merck Collaboration Agreement during the three and nine months ended September 30, 2024, and recognized $26.7 million and $31.1 million of revenue under the Merck Collaboration Agreement during the three and nine months ended September 30, 2023, respectively. Over the course of the Merck Collaboration Agreement through September 30, 2024, the Company received $39.9 million in payments from Merck, of which $30.0 million related to the upfront fee, and $9.9 million related to reimbursable research services.

Affimed Collaboration Agreement

On November 1, 2022, the Company entered into a strategic collaboration agreement with Affimed GmbH, a subsidiary of Affimed N.V. ("Affimed") for the clinical development and commercialization of a combination therapy, for any uses in humans or animals, comprising Affimed's product consisting of an innate cell engager referred to as "AFM13" and the Company's product containing an NK cell referred to as AB-101 (the "Affimed Collaboration Agreement"). While the collaboration is initially limited to the United States, the parties will, upon Affimed's request, in good faith discuss an expansion to certain other territories.

The Company has granted Affimed, with respect to the development of the combination therapy an exclusive, and with respect to the promotion of the combination therapy under the Affimed Collaboration Agreement a non-exclusive, non-transferable (except to affiliates and successors in interest), royalty-free and non-sublicensable (with certain exceptions) license under relevant Company patents and know-how. Affimed has granted the Company a non-exclusive, non-transferable (except to affiliates and successors in interest), royalty-free license and non-sublicensable (with certain exceptions) license under relevant Affimed patents and know-how for use in the clinical development of the combination therapy under the Affimed Collaboration Agreement.

The financial terms of the Affimed Collaboration Agreement provides that Affimed shall be responsible for all costs associated with the development of the combination therapy (including all clinical trial costs), except that Affimed and the Company shall each bear 50% of the costs and expenses incurred in connection with the performance of any confirmatory combination therapy clinical trial required by the FDA. The Company shall be solely responsible for all costs incurred by the Company for the supply of AB-101 and IL-2 product used in the clinical trials for the combination therapy, and for carrying out activities assigned to it under the agreed development plan. In addition, under the Affimed Collaboration Agreement, the parties agree to make payments to each other to achieve a proportion of 67%/33% (Affimed/Company) of revenues generated by both parties from commercial sales of each party's product as part of the combination therapy.

The Company incurred zero and $0.1 million of expense in connection with the Affimed Collaboration Agreement during the three and nine months ended September 30, 2024, respectively, and zero and $0.7 million of expense in connection with the Affimed Collaboration Agreement during the three and nine months ended September 30, 2023, respectively.

9. Convertible Preferred Stock and Stockholders' Equity (Deficit)

Stockholders' Equity (Deficit)

Under the Amended and Restated Certificate of Incorporation dated July 22, 2024, the Company had a total of 710,000,000 shares of capital stock authorized for issuance, consisting of 700,000,000 shares of common stock, par value of $0.0001 per share, and 10,000,000 shares of preferred stock, par value of $0.0001 per share. Additionally, the Company has authorized 84,556 shares reserved under the terms specified as part of the Company's Pledge 1% Movement commitment, in support of its corporate social responsibility and philanthropic pursuits.

Convertible Preferred Stock

In 2020 and 2021, the Company issued 2,077,165 shares and 1,595,983 shares, respectively, of Series A convertible preferred stock at a price of $21.93 per share, resulting in aggregate gross proceeds of $70.0 million and total issuance costs of $0.4 million. The Company converted a promissory note with a fair value of $10.6 million as part of the first closing and reclassified a convertible preferred stock purchase right liability with a fair value of $23.7 million into equity as part of the second closing.

In 2021, the Company issued 2,487,237 shares of Series B convertible preferred stock at a price of $48.25 per share resulting in aggregate gross proceeds of $120.0 million and incurred $0.4 million of total issuance costs.

As of December 31, 2023, the Company's Series A and Series B convertible preferred stock has been classified as temporary equity in the accompanying condensed balance sheets given that the holders of the convertible preferred stock could cause certain events to occur that are outside of the Company's control whereby the Company could be obligated to redeem the convertible preferred stock. The carrying value of the convertible preferred stock was not adjusted to the redemption value until the contingent redemption events are considered to be probable of occurring.

Immediately upon completion of the IPO, 6,160,385 outstanding shares of convertible preferred stock converted into 6,160,385 shares of common stock. There are no Series A or Series B convertible preferred shares outstanding as September 30, 2024.

Common Stock

The voting, dividend, and liquidation rights of the holders of the common stock are subject to, and qualified by, the rights, preferences and privileges of the holders of the Series A and Series B convertible preferred stock. The holders of the common stock are entitled to one vote for each share of common stock held at all meetings of stockholders.

Common stock reserved for future issuance consisted of the following:

	AS OF	
	SEPTEMBER 30, 2024	DECEMBER 31, 2023
Convertible preferred stock	—	6,160,385
Common stock options granted and outstanding	2,238,816	1,315,726
Restricted stock units granted and outstanding	533,484	22,514
Shares available for issuance under the 2024 and 2020 equity incentive plans, respectively	1,798,605	323,131
Shares available for issuance under the ESPP Plan	212,000	—
Shares available for issuance under the Pledge 1% commitment	84,556	84,556
Total common stock reserved for future issuance	4,867,461	7,906,312

Stock Options

In June 2020, the Company adopted the 2020 Equity Incentive Plan (the "Plan"). The Plan provides for the grant of incentive stock options ("ISO"), non-statutory stock options ("NSO"), stock appreciation rights, restricted stock awards, restricted stock unit awards, and other stock awards.

The Plan was amended in December 2020, January 2021, July 2021, August 2022, and in April 2024. In April 2024, the Plan was amended to increase the total number of shares reserved under the Plan to 2,083,797.

In July 2024, in connection with the closing of the IPO, the Company's board of directors adopted the 2024 Equity Incentive Plan (the "2024 Plan"), a successor to and continuation of the 2020 Plan. Upon the effectiveness of the 2024 Plan, 4,572,025 shares of common stock were authorized for issuance which consists of (1) 2,630,000 new shares of common stock, (2) 115,436 shares available for issuance under the 2020 Plan, and (3) up to 1,826,589 shares of common stock subject to outstanding stock awards granted under the 2020 Plan that, on or after the 2024 Plan becomes effective, expire or otherwise terminate prior to exercise or settlement; are not issued because the stock award is settled in cash; are forfeited or repurchased because of the failure to vest; or are reacquired or withheld to satisfy a tax withholding obligation or the purchase or exercise price, if any, as such shares become available from time to time. Furthermore, upon effectiveness of the 2024 Plan, no further grants will be made under the 2020 Plan, and the 2020 Plan will automatically terminate on June 23, 2030.

Options granted under the 2024 Plan are exercisable at various dates as determined upon grant and will expire no more than 10 years from their date of grant. The exercise price of each option shall be determined by the board of directors based on the estimated fair value of the Company's stock on the date of the option grant. The exercise price shall not be less than 100% of the fair market value of the Company's common stock at the time the option is granted. Most option grants generally vest 25% on the first anniversary of the original vesting commencement date, with the balance vesting monthly over the remaining three years and early exercise is permitted. The vesting period generally occurs over four years unless there is a specific performance vesting trigger at which time those shares will vest when the performance trigger is probable to occur.

On April 6, 2023, the Company's board of directors approved a stock option repricing (the "Option Repricing") in which the exercise price of certain outstanding options to purchase shares of the Company's common stock under the 2020 Plan was reduced to $5.01 per share, the estimated fair value of the Company's common stock as of December 31, 2022. The Option Repricing was intended to motivate holders of options with exercise prices in excess of the estimated fair value of the Company's common stock to remain with the Company and work toward its success. The Option Repricing included options granted pursuant to the 2020 Plan that were held by, among others, members of the Company's board of directors and the Company's named executive officers.

As a result of the Option Repricing, 1,168,651 shares of vested and unvested stock options outstanding as of April 6, 2023, with original exercise prices ranging from $5.14 to $51.72 per share, were repriced to an exercise price of $5.01 per share. The Option Repricing impacted 70 grantees and the total incremental fair value recognized as a result of the repricing was $1.5 million.

A summary of the Company's stock option activity under the 2020 and 2024 Plan for the nine months ended September 30, 2024 is as follows:

	TOTAL OPTIONS	WEIGHTED-AVERAGE EXERCISE PRICE PER SHARE	WEIGHTED-AVERAGE REMAINING CONTRACTUAL TERM (in years)	AGGREGATE INTRINSIC VALUE (in thousands)
Outstanding at December 31, 2023	1,315,726	$ 5.02	9.1	$ 214
Granted	996,389	11.21	—	—
Exercised	(5,583)	5.00	—	—
Cancelled	(67,716)	6.56	—	—
Outstanding at September 30, 2024	2,238,816	$ 7.72	8.9	$ 17,307
Exercisable as of September 30, 2024	1,064,579	$ 5.02	8.4	$ 11,101

The weighted-average grant date fair value of options granted for the nine months ended September 30, 2024 and 2023, was $8.85 and $3.29 per share, respectively. The total intrinsic value of options exercised during the nine months ended September 30, 2024 and 2023, was de minimus. Upon the exercise of stock options, the Company will issue new shares of its common stock.

Employee Stock Purchase Plan

In connection with the closing of the IPO, the Company's board of directors adopted the 2024 Employee Stock Purchase Plan (the "ESPP"). The ESPP provides for two-year offering periods consisting of four 6-month purchase periods, and at the end of each purchase period employees are able to purchase shares at 85% of the lower of the fair market value of the Company's common stock on the first trading day of the offering period or on the last trading day of the purchase period. A new offering is initiated each January 16 and July 16. In the event the fair market value of the Company's common stock on the first day of any new offering is less than or equal to the fair market value of a ongoing offering, the ongoing offering shall terminate immediately following the purchase of shares of common stock on the purchase date immediately preceding the new offering and participants in the terminated ongoing offering will be automatically enrolled in the new offering.

An aggregate of 212,000 shares were initially reserved and available for issuance under the ESPP. The ESPP provides that the number of shares reserved and available for issuance under the plan will automatically increase each January 1, beginning on January 1, 2025, by the lesser of 1.0% of the outstanding number of shares of common stock on the immediately preceding December 31, and 424,000 shares of common stock. No awards were granted under the ESPP as of September 30, 2024.

Restricted Stock Unit Awards

Restricted stock unit awards ("RSUs") granted under the 2020 and 2024 Plan are subject to time-based vesting and convert to shares of common stock in accordance with the vesting schedule. RSUs are valued at the estimated fair value of the Company's stock on the date of grant and are amortized over the requisite service period. The total number of RSUs granted represents the maximum number of RSUs eligible to vest based upon the service conditions set forth in the grant agreements. Employees forfeit unvested RSUs upon termination of employment with a corresponding reversal of expense.

During the nine months ended September 30, 2024 and 2023, 513,620 and zero RSUs were granted by the Company, respectively. As of September 30, 2024, 533,484 total RSUs were outstanding.

Stock-Based Compensation Expense

The following table summarizes stock-based compensation expense by condensed financial statement line item in the Company's statement of operations and comprehensive income (loss) (in thousands):

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2024	2023	2024	2023
Research and development	$ 888	$ 791	$ 2,452	$ 2,880
General and administrative	1,019	580	2,344	2,781
Total	$ 1,907	$ 1,371	$ 4,796	$ 5,661

In 2023, the Company entered into separation agreements with certain executives, terminating their employment and entering into consulting agreements. Under the separation agreements, service-based requirements for one of the executives were deemed satisfied for all RSUs as of the date of separation. In order for RSUs to vest, there must be a liquidity event and the RSUs must meet the time and service-based requirement prior to the defined Liquidity Event Deadline. There were no outstanding RSUs associated with these executives as of September 30, 2024. The Company recognized zero in incremental compensation cost for the three and nine months ended September 30, 2024, and $0.5 million in incremental compensation cost for the three and nine months ended September 30, 2023. The separation agreements also provided for extended vesting terms of certain options grants through the term of the consulting agreements. The Company recognized zero in incremental compensation cost for the three and nine months ended September 30, 2024, and zero and $0.2 million in incremental compensation cost for the three and nine months ended September 30, 2023, respectively.

The assumptions used in the Black-Scholes option pricing model to determine the fair value of the employee and nonemployee stock option grants issued for the nine months ended September 30, 2024 and 2023, were as follows:

	NINE MONTHS ENDED SEPTEMBER 30,	
	2024	2023
Stock price	$5.18 - $15.45	$ 5.00
Risk-free rate of interest	3.5% - 4.6%	3.6% - 4.4%
Expected term (years)	5.1 - 6.1	5.5 - 6.1
Expected stock price volatility	87.4% - 110.5%	86.5% - 88.6%
Expected dividend yield	—	—

As of September 30, 2024, the unrecognized compensation cost related to outstanding employee and non-employee options was $12.2 million and is expected to be recognized as expense over a weighted-average period of 2.9 years. As of September 30, 2024, the unrecognized compensation cost related to outstanding RSUs was $5.7 million and is expected to be recognized as expense over a weighted-average period of 3.9 years.

10. Related Party Transactions

Relationship with GC Cell and GC Corp

GC Cell and GC Corp, subsidiaries of Green Cross Corp, are stockholders of the Company and are represented on the Company's board of directors.

In November 2019, October 2020, March 2021, and December 2022, the Company entered into a license agreement (collectively, the "License Agreements") with GC Cell (see Note 8). In August 2020, the Company entered into a Research and Service Agreement with GC Cell in which GC Cell is to provide mutually agreed research services in support of the research and development of one or more of the Selected Products that the Company has licensed from GC Cell under the License Agreements. The Company did not incur any research and development expense in connection with the agreements for the three and nine months ended September 30, 2024 and 2023. As of September 30, 2024 and December 31, 2023, the Company had no accounts payable and accrued expenses in connection with the GC Cell License Agreements and Research Service Agreement.

In September 2023, the Company and GC Cell amended the AB-201 Agreement (see Note 8). The Company recognized zero and $0.3 million of license and development support-related revenue for the three and nine months ended September 30, 2024, respectively, on its condensed statements of operations and comprehensive income (loss), related to GC Cell's achievement of a defined development milestone and development support activities under the Amended AB-201 Agreement. As of September 30, 2024 and December 31, 2023, total accounts receivable related to the Amended AB-201 Agreement were $0.6 million and $0.6 million, respectively.

Under the AB-205 Agreement, GC Cell agreed to reimburse the Company for Direct Costs incurred on behalf of GC Cell in accordance with the Development Plan under the AB-205 Agreement, provided that such reimbursed costs are deemed to form part of the Direct Costs incurred and paid by GC Cell (see Note 8). Total reimbursements for development costs invoiced to GC Cell in connection with the AB-205 Agreement were zero and $0.1 million for the three and nine months ended September 30, 2024, respectively, and $0.5 million and $1.0 million for the three and nine months ended September 30, 2023, respectively. During the three and nine months ended September 30, 2024, the Company received payments from GC Cell in the amounts of $0.7 million and $1.7 million, respectively. As of September 30, 2024 and December 31, 2023, the Company had zero and $0.6 million recorded in the condensed balance sheets as other receivable, respectively.

In March 2020, the Company entered into the Manufacturing Agreement with GC Cell, where GC Cell is to perform manufacturing services with respect to any biological or chemical product manufactured or to be manufactured for use in Phase 1 or Phase 2 clinical trials. The Company amended the Manufacturing Agreement in June 2020 to include the Company's right to terminate the agreement at will. The Company incurred $1.2 million and $2.7 million of research and development expenses in connection with the agreement for the three and nine months ended September 30, 2024, respectively, and $1.4 million and $3.2 million of research and development expenses in connection with the agreement for the three and nine months ended September 30, 2023, respectively. As of September 30, 2024 and December 31, 2023, the Company had $1.6 million and $2.4 million, respectively, of accounts payable and accrued expenses in connection with the Manufacturing Agreement recorded in the condensed balance sheets.

In January 2021, concurrent with entering into the Merck Collaboration Agreement, the Company also entered into a Partnered Program License Agreement with GC Cell to obtain exclusive, worldwide rights to GC Cell's CAR-NK technology with respect to the licensed products and to engage GC Cell to perform services in support of the research programs. The Company agreed to reimburse GC Cell for research and development services as these services were provided. The Company was required to pay GC Cell 100% of regulatory milestones, sales milestones and royalty payments received by Merck relating to products in Asia, Australia and New Zealand and 50% of upfront payments, license fees, regulatory milestones, sales milestones and royalty payments received by Merck relating to products in all other territories. In October 2023, the Merck Collaboration Agreement and development thereunder was terminated by Merck.

Relationship with RA Capital

RA Capital Healthcare Fund, L.P., RA Capital Nexus Fund, L.P. and Blackwell Partners LLC—Series A (the "RA Capital Funds") are stockholders of the Company and a member of the Company's board of directors is affiliated with the RA Capital Funds.

In June 2024, the Company entered into a services agreement (the "Blackbird Services Agreement") with Blackbird Clinical, Inc. ("Blackbird"), an entity controlled by RA Capital Management, L.P. RA Capital Management, L.P. is the investment manager for the RA Capital Funds. Under the terms of the Blackbird Services Agreement, Blackbird provides consulting services in connection with the Company's clinical trials, including study strategy, clinical operations and patient operations. The Company incurred $0.1 million of research and development expenses in connection with the consulting services from Blackbird for the three and nine months ended September 30, 2024. No expenses were incurred with Blackbird for the three and nine months ended September 30, 2023. As of September 30, 2024, and December 31, 2023, the Company had $57 thousand and zero of accounts payable and accrued expenses, respectively, in connection with the Blackbird Services Agreement recorded in the condensed balance sheets.

11. Commitments and Contingencies

Operating Leases

The following table presents operating rent expense and related short-term lease costs (in thousands):

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2024	2023	2024	2023
Rent expense	$ 1,003	$ 1,056	$ 3,043	$ 3,091
Amount of rent expense related to short-term leases	68	71	203	214

Future minimum annual obligations under the Company's operating leases with terms in excess of one year are as follows (in thousands):

PERIOD ENDED SEPTEMBER 30,	
2024 (remaining)	1,017
2025	4,007
2026	3,418
2027	3,520
Thereafter	5,916
Total minimum lease payments	17,878
Less: amount representing interest	(3,104)
Present value of operating lease liabilities	14,774
Less: operating lease liabilities, current	(3,614)
Operating lease liabilities, net of current portion	$ 11,160

As the Company's leases do not provide an implicit rate, the Company uses an incremental borrowing rate based on average discount rate were as follows:

	AS OF	
	SEPTEMBER 30, 2024	DECEMBER 31, 2023
Weighted-average remaining lease term	4.6 years	5.3 years
Weighted-average discount rate	7.7%	7.8%

On July 22, 2022, the Company entered into a sublease (the "Sublease Agreement") with Origis Operating Services, LLC, (the "Sublessee"), whereby the Company agreed to sublease to Sublessee all of the 13,405 rentable square feet of office space in San Diego, California currently leased by the Company under the Executive Drive Lease. The sublease commenced on August 1, 2022, and has a term through December 31, 2025. The aggregate base rent is approximately $2.6 million commencing August 1, 2022. The Company records sublease income as a reduction of general and administrative expense.

The expected undiscounted cash flows to be received from the sublease are as follows (in thousands):

PERIOD ENDED SEPTEMBER 30,	
2024 (remaining)	$ 215
2025	873
Total	$ 1,088

The Company recognized $0.2 million and $0.6 million of sublease income for the three and nine months ended September 30, 2024, respectively and $0.2 million and $0.6 million of sublease income for the three and nine months ended September 30, 2023, respectively.

12. Subsequent Events

For the purposes of the condensed financial statements as of September 30, 2024, and the three and nine months then ended, the Company has evaluated the subsequent events through November 12, 2024, the date the condensed financial statements were issued.

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

The following discussion and analysis of our financial condition and results of operations and the unaudited interim condensed financial statements and related notes included in this Quarterly Report on Form 10-Q should be read in conjunction with the financial statements and related notes thereto as of and for the year ended December 31, 2023 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in the prospectus filed on July 22, 2024, pursuant to Rule 424(b) under the Securities Act of 1933, as amended (the Securities Act), with the Securities and Exchange Commission (the SEC) , or the Prospectus. This discussion and analysis and other parts of this Quarterly Report on Form 10-Q contain forward-looking statements based upon current beliefs, plans and expectations related to future events and our future financial performance that involve risks, uncertainties and assumptions, such as statements regarding our intentions, plans, objectives and expectations for our business. Our actual results and the timing of selected events could differ materially from those described in or implied by these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the sections of this Quarterly Report on Form 10-Q entitled "Special Note Regarding Forward-Looking Statements" and "Risk Factors," under Part II, Item 1A.

Overview

We are a clinical-stage biotechnology company focused on developing natural killer (NK) cell-based therapies for patients suffering from devastating autoimmune diseases and cancers. Our product candidates are derived from donor cells (allogeneic) rather than a patient's own cells (autologous) and are pre-manufactured, stored frozen and ready to ship to a patient's treatment location, making them what we believe to be "off-the-shelf." Our lead product candidate, AlloNK, is a non-genetically modified, cryopreserved NK cell therapy being evaluated in combination with B-cell targeted monoclonal antibodies (mAbs) in an ongoing Phase 1/1b trial in systemic lupus erythematosus (SLE) with or without lupus nephritis (LN) and a basket investigator-initiated trial (IIT) in multiple autoimmune indications. Seminal peer-reviewed clinical studies using autologous CD19 chimeric antigen receptor (CAR) T-cell therapy (auto-CAR-T) for the treatment of autoimmune diseases have demonstrated that deep B-cell depletion in the periphery and in the lymphoid tissue can lead to drug free disease remission. We have already demonstrated that AlloNK in combination with rituximab was able to drive deep B-cell depletion in the periphery and observed complete responses (CRs) in heavily pre-treated patients naïve to auto-CAR-T in our ongoing Phase 1/2 clinical trial in patients with relapsed or refractory B-cell non-Hodgkin lymphoma (B-NHL). We believe the preliminary results from our Phase 1/2 clinical trial evaluating AlloNK in combination with rituximab in patients with B-NHL provide a readthrough to autoimmune disease because efficacy in both diseases appears to be accomplished with a shared mechanism of action involving B-cell depletion in the periphery and in the lymphoid tissues, followed by an immunological reset and B-cell reconstitution. We expect to report initial data on autoimmune indications from at least one of our Phase 1/1b trial or the basket IIT in the first half of 2025.

We commenced our operations in 2019 and have devoted substantially all of our resources to date to organizing and staffing our company, business planning, raising capital, establishing and engaging in collaborations, conducting research and development, advancing and scaling up product candidate manufacturing, establishing cold chain delivery logistics, establishing and protecting our intellectual property portfolio and providing general and administrative support for these activities. From our inception through September 30, 2024, we have raised aggregate gross proceeds of $8.0 million from the issuance and sale of convertible promissory notes, $70.0 million from our Series A convertible preferred stock financings, $120.0 million from our Series B convertible preferred stock financing and $24.4 million from our SAFEs. Additionally, in July 2024, we closed on our initial public offering (IPO), in which we issued and sold 13,920,000 shares of common stock at a public offering price of $12.00 per share. We also sold an additional 1,000,000 shares of common stock upon the partial exercise of the underwriters' purchase option. The aggregate net proceeds of the IPO, inclusive of the partial exercise of the underwriters' purchase option and after deducting underwriting discounts, commissions, and offering expenses, was $162.3 million.

We have incurred significant operating losses since the commencement of our operations. We have never generated any revenue from product sales and do not expect to generate any revenues from product sales unless and until we successfully complete development of and obtain regulatory approval for our product candidates, which will not be for several years, if ever. In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution.

We have incurred a net loss of $49.3 million and $16.7 million during the nine months ended September 30, 2024 and 2023, respectively, and $28.7 million and $58.8 million during the years ended December 31, 2023 and 2022, respectively. As of September 30, 2024, we had an accumulated deficit of $230.6 million, cash, cash equivalents and investments of $199.6 million. We expect to continue to incur significant losses for the foreseeable future as we advance our current and future product candidates through preclinical and clinical development, continue to build our operations and transition to operating as a public company. Accordingly, until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our cash needs through public or private equity or debt financings or other capital sources, which may include our existing and any future strategic collaborations and other strategic arrangements with third parties. However, we may not be able to raise additional funds or enter into such other arrangements when needed or on favorable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration or licensing arrangements with third parties or other strategic transactions, we may have to relinquish rights to our intellectual property, future revenue streams, research programs, or product candidates or grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. If we are unable to raise additional capital or enter into such arrangements when needed, we could be forced to delay, limit, reduce or terminate our research and development programs or future commercialization efforts, or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves.

The manufacturing of our cell therapy products is novel and complex, and we have invested substantial resources to optimize the manufacturing process of our product candidates, including selection and optimization of cord blood units, establishing cold chain supply logistics and leveraging the current Good Manufacturing Practices (cGMP) manufacturing facility of GC Cell Corporation (GC Cell) to expand NK cells and create our product candidates. We also currently operate manufacturing facilities at our leased facility in San Diego, California to support NK and CAR-NK cell production for our pipeline development and clinical trial (and potentially commercial) supply. We also currently rely on other third-parties to ship and store our cord blood units and drug product lots, viral vectors and master and working feeder cell banks, as well as other components used in the manufacturing process for our product candidates, and we expect to continue to do so to meet our preclinical, clinical, and potential commercial activities. We expect that we and GC Cell will be capable of providing and processing sufficient quantities of our product candidates to meet anticipated clinical trial demands cost-effectively. However, any disruption in the supply or manufacture of our product candidates could result in delays in our preclinical studies and clinical trials and increase the costs of our research and development activities. We plan to continue to invest in our manufacturing capability and cryopreservation techniques to continuously improve our production and supply chain capabilities over time.

Components of Results of Operations

Collaboration Revenue

As of September 30, 2024, we have not generated any revenues from product sales or royalties. Our revenues have been derived from the Exclusive License and Research Collaboration Agreement (the Merck Collaboration Agreement) with Merck Sharp & Dohme Corp. (Merck) and a license agreement with GC Cell for our AB-201 product candidate, as amended in February 2022 and September 2023 (the AB-201 Agreement).

In January 2021, we entered into the Merck Collaboration Agreement which was subsequently terminated in October 2023, pursuant to which we received an upfront, non-refundable and non-creditable payment of $30.0 million for two target programs, with an additional $15.0 million payable by Merck if we and Merck agreed upon a third collaboration target.

Additionally, we were entitled to be reimbursed for the conduct of each research program, including external research costs and manufacture and supply of clinical materials for Phase 1 clinical trials, up to $14.0 million per program.

We concluded that Merck represented a customer and in accordance with Accounting Standards Codification (ASC) 606, we determined that the initial transaction price under the Merck Collaboration Agreement equals $58.0 million, consisting of the upfront, non-refundable and non-creditable payment of $30.0 million and the aggregate estimated research and development fees of $28.0 million. The initial transaction price was allocated evenly to each of the two product targets. In addition, we identified our performance obligations under the Merck Collaboration Agreement, including our grant to Merck of a license to certain of our intellectual property subject to certain conditions, our conduct of research services, and our participation in a joint research committee. We determined that all performance obligations should be accounted for as one combined performance obligation for each target program, and that since no individual performance obligation is distinct, and that the combined performance obligation is transferred over the expected term of the conduct of the research services, which is estimated to be four years which represents the combined terms for the research programs. Upon termination of the Merck Collaboration Agreement, we recognized the remaining portion of the upfront, non-refundable $30.0 million in revenue.

Collaboration revenues recognized under the Merck Collaboration Agreement were zero and $26.7 million for the three months ended September 30, 2024 and 2023, respectively, and zero and $31.1 million during the nine months ended September 30, 2024 and 2023, respectively.

License and Development Support Revenue

License and development support-related revenues related to GC Cell's development support activities under the AB-201 Agreement were zero during the three months ended September 30, 2024 and 2023, and $0.3 million and zero during the nine months ended September 30, 2024 and 2023, respectively.

Operating Expenses

Our operating expenses consist of (i) research and development expenses and (ii) general and administrative expenses.

Research and Development

Our research and development expenses consist primarily of external and internal costs related to the development of product candidates.

External costs include:

•expenses incurred in connection with research, laboratory consumables and preclinical studies;

•expenses incurred in connection with conducting clinical trials including investigator grants and site payments for time and pass-through expenses and expenses incurred under agreements with contract research organizations (CROs) other vendors or central laboratories and service providers engaged to conduct our trials;

•the cost of consultants engaged in research and development related services and the cost to manufacture cell therapy product candidates for use in our clinical trials and preclinical studies;

•costs related to regulatory compliance; and

•the cost of annual license fees.

Internal costs include:

•personnel-related expenses, including salaries and related benefits, travel and stock-based compensation expenses for personnel engaged in research and development functions; and

•facilities, depreciation, and other expenses, which include allocated expenses for rent and maintenance of facilities, insurance and supplies.

Research and development expenses are recognized as incurred and payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received. We track outsourced development, outsourced personnel costs and other external research and development costs of specific programs. We do not track our internal research and development costs on a program-by-program basis because these costs are associated with multiple programs and, as such, are not separately classified.

Research and development activities are central to our business model. There are numerous factors associated with the successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. In addition, future regulatory factors beyond our control may impact our development programs. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials.

At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of any of our product candidates. However, we expect that our research and development expenses will increase substantially in connection with our planned preclinical and clinical development activities in the near term and in the future.

General and Administrative

General and administrative expenses consist of personnel-related expenses, including salaries and related benefits, travel and stock-based compensation expenses for personnel engaged in executive, finance and other administrative functions. Other significant costs include facilities-related costs, legal fees relating to intellectual property and corporate matters, professional fees for accounting and consulting services and insurance costs. We expect that our general and administrative expenses will increase substantially for the foreseeable future to support our continued research and development activities, pre-commercial preparation activities for our product candidates, and, if any product candidate receives marketing approval, commercialization activities. Following the completion of this offering, we also anticipate increased expenses related to audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums and investor relations costs associated with operating as a public company.

Interest Income

Interest income consists of interest on our money market funds and short-term and long-term investments.

Change in Fair Value of Simple Agreement for Future Equity

In 2023, we issued $24.4 million of SAFEs to various existing investors and related parties. The SAFEs are recorded as liabilities at fair value and remeasured at fair value at each reporting period. The change in fair value for the period is recorded in change in fair value of SAFEs in the statements of operations.

In connection with the closing of the IPO, the outstanding SAFEs converted into 2,391,418 shares of common stock.

Other Income (Expense), Net

Other income (expense), net consists primarily of realized gains and losses on short-term investments.

Income Taxes

Provision for income taxes consists of U.S. federal and state income taxes in which we conduct business. Since our inception, we have not recorded any income tax benefits for the net losses we have incurred in each year or for our research and development tax credits, as we believe, based upon the weight of available evidence, that it is more likely than not that all of our net operating loss (NOL) carryforwards and tax credits will not be realized. Accordingly, we have recorded a full valuation allowance against our net deferred tax assets at September 30, 2024 and December 31, 2023.

Results of Operations

Comparison of the Three Months Ended September 30, 2024 and 2023

The following table summarizes our results of operations for the three months ended September 30, 2024 and 2023 (in thousands):

	FOR THE THREE MONTHS ENDED SEPTEMBER 30,		
	2024	2023	CHANGE
Revenue:			
Collaboration revenue	$ —	$ 26,656	$ (26,656)
Total revenue	—	26,656	(26,656)
Operating expenses:			
Research and development	13,524	13,065	459
General and administrative	4,811	2,780	2,031
Total operating expenses	18,335	15,845	2,490
Income (loss) from operations	(18,335)	10,811	(29,146)
Other income (expense), net:			
Interest income	1,846	418	1,428
Change in fair value of SAFEs	(977)	—	(977)
Other income (expense), net	(6)	50	(56)
Total other income (expense), net	863	468	395
Net income (loss)	$ (17,472)	$ 11,279	$ (28,751)
Unrealized gain on investments	217	144	73
Comprehensive income (loss)	$ (17,255)	$ 11,423	$ (28,678)

Collaboration Revenue. Collaboration revenues were $26.7 million for the three months ended September 30, 2023, related to the Merck Collaboration Agreement. The $26.7 million consisted of $23.8 million of recognition of revenue from the deferred up-front payment and $2.9 million in reimbursement revenues.

Research and Development Expenses. We track outsourced development, outsourced personnel costs and other external research and development costs of specific programs. We do not track our internal research and development costs on a program-by-program basis. The following table summarizes our research and development expenses for the three months ended September 30, 2024 and 2023 (in thousands):

	THREE MONTHS ENDED SEPTEMBER 30,	
	2024	2023
External research and development expense:		
AB-101	$ 5,399	$ 3,862
AB-201	31	80
Merck 1	—	1,142
Merck 2	—	42
Other programs	108	319
Internal research and development expense:		
Personnel-related	5,063	4,573
Other	2,923	3,047
Total research and development expense	$ 13,524	$ 13,065

Research and development expenses were $13.5 million for the three months ended September 30, 2024, compared to $13.1 million for the three months ended September 30, 2023. The increase of $0.5 million was primarily due to a $0.4 million increase in internal research and development expense, and a $0.1 million increase in external research and development expense. The $0.4 million increase in internal research and development expense is primarily due to a $0.5 million increase in personnel-related expenses supporting our additional headcount as we expanded the number of research and development employees to support our programs, inclusive of an increase of $0.1 million of non-cash stock-based compensation expense, offset by a $0.1 million decrease in other operating costs. The $0.1 million increase in external research and development expense is primarily due to increases of $1.5 million of AB-101 costs related to product candidate development and clinical trials as we progressed towards the end of our clinical trial for the B-NHL program and commenced our clinical trial on the AlloNK for SLE/LN program, offset by decreases of $0.2 million in other program costs and $1.2 million in Merck Collaboration Agreement costs due to the termination of the agreement.

General and Administrative Expenses. General and administrative expenses were $4.8 million for the three months ended September 30, 2024, compared to $2.8 million for the three months ended September 30, 2023. The increase of $2.0 million for the three months ended September 30, 2024, was primarily comprised of a $1.2 million increase in personnel-related costs including a $0.8 increase in personnel operating costs and a $0.4 million increase in non-cash stock-based compensation, in addition to a $0.7 million increase in operational costs and a $0.1 million increase in legal costs.

Other Income (Expense), Net. Other income was $0.9 million for the three months ended September 30, 2024, compared to other income of $0.5 million for the three months ended September 30, 2023. The increase of $0.4 million was primarily due to a $1.4 million increase in dividend and interest income due to more favorable rates of return during 2024 and higher investment balances, partially offset by a $1.0 million change in fair value of SAFEs, which we entered into in late 2023.

Unrealized Gain (Loss) on Investments. Unrealized gain on investments was $0.2 million for the three months ended September 30, 2024, compared to an unrealized gain of $0.1 million for the three months ended September 30, 2023. The increase of $0.1 million was primarily due to the change in fair value of available-for-sale securities purchased subsequent to September 30, 2023.

Comparison of the Nine Months Ended September 30, 2024 and 2023

The following table summarizes our results of operations for the nine months ended September 30, 2024 and 2023 (in thousands)

	FOR THE NINE MONTHS ENDED SEPTEMBER 30,		
	2024	2023	CHANGE
Revenue:			
Collaboration revenue	$ —	$ 31,142	$ (31,142)
License and development support revenue	251	—	251
Total revenue	251	31,142	(30,891)
Operating expenses:			
Research and development	37,011	39,098	(2,087)
General and administrative	12,255	10,745	1,510
Total operating expenses	49,266	49,843	(577)
Loss from operations	(49,015)	(18,701)	(30,314)
Other income (expense), net:			
Interest income	3,172	1,952	1,220
Change in fair value of SAFEs	(3,597)	—	(3,597)
Other income (expense), net	162	27	135
Total other income (expense), net	(263)	1,979	(2,242)
Net loss	$ (49,278)	$ (16,722)	$ (32,556)
Unrealized gain on investments	30	271	(241)
Comprehensive loss	$ (49,248)	$ (16,451)	$ (32,797)

Collaboration Revenue. Collaboration revenues were $31.1 million for the nine months ended September 30, 2023, related to the Merck Collaboration Agreement. The $31.1 million consisted of $25.2 million of recognition of revenue from the deferred up-front payment and $5.9 million in reimbursement revenues.

License and Development Support Revenue. License and development support revenues were $0.3 million for the nine months ended September 30, 2024, compared to zero for the nine months ended September 30, 2023. Revenues were related to development support activities under the AB-201 Agreement.

Research and Development Expenses. We track outsourced development, outsourced personnel costs and other external research and development costs of specific programs. We do not track our internal research and development costs on a program-by-program basis. The following table summarizes our research and development expenses for the nine months ended September 30, 2024 and 2023 (in thousands):

	NINE MONTHS ENDED SEPTEMBER 30,	
	2024	2023
External research and development expense:		
AB-101	$ 13,245	$ 10,603
AB-201	88	350
Merck 1	—	1,927
Merck 2	—	424
Other programs	156	1,259
Internal research and development expense:		
Personnel-related	14,596	15,303
Other	8,926	9,232
Total research and development expense	$ 37,011	$ 39,098

Research and development expenses were $37.0 million for the nine months ended September 30, 2024, compared to $39.1 million for the nine months ended September 30, 2023. The decrease of $2.1 million was primarily due to a $1.1 million decrease in external research and development expense, and a $1.0 million decrease in internal research and development expense. The $1.1 million decrease in external research and development expense is primarily due to a decrease of $2.3 million in Merck costs due to the termination of the agreement, in addition to a $1.4 million decrease in other programs as we narrowed our research focus to our AB-101 programs, offset by a $2.6 million increase in AB-101 costs related to product candidate development and clinical trials as we progressed towards the end of our clinical trial for the B-NHL program and commenced our clinical trial on the AlloNK for SLE/LN program. The $1.0 million decrease in internal research and development expense is primarily due a $0.7 million decrease in personnel-related expenses, inclusive of a decrease of $0.4 million of non-cash stock-based compensation expense, as a result of the reduction in work force in March 2023, in addition to a $0.3 million decrease in other operating costs.

General and Administrative Expenses. General and administrative expenses were $12.3 million for the nine months ended September 30, 2024, compared to $10.7 million for the nine months ended September 30, 2023. The increase of $1.5 million for the nine months ended September 30, 2024, was primarily comprised of a $1.1 million increase in operational costs and a $0.2 million increase in legal costs, in addition to a $0.2 million increase in personnel-related costs including a $0.6 increase in personnel operating costs offset by a $0.4 million decrease in non-cash stock-based compensation.

Other Income (Expense), Net. Other expense was $0.3 million for the nine months ended September 30, 2024, compared to other income of $2.0 million for the nine months ended September 30, 2023. The decrease of $2.2 million was primarily due to the $3.6 million change in fair value of SAFEs, which we entered into in late 2023, offset by a $1.2 million increase in dividend and interest income due to more favorable rates of return during 2024 and by a $0.2 million increase in other income.

Unrealized Gain (Loss) on Investments. Unrealized gain on investments was $30 thousand for the nine months ended September 30, 2024, compared to an unrealized gain of $0.3 million for the nine months ended September 30, 2023. The decrease of $0.3 million in the year ended December 31, 2023 was primarily due to the change in fair value of available-for-sale securities purchased subsequent to September 30, 2023.

Liquidity and Capital Resources

Sources of Liquidity

We have incurred net losses and negative cash flows from operations since our inception and expect to continue to incur significant and increasing operating losses for the foreseeable future. We have never generated any revenue from product sales and do not expect to generate any revenues from product sales unless and until we successfully complete development of and obtain regulatory approval for our product candidates, which will not be for several years, if ever. In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales,

marketing, manufacturing and distribution. From our inception through September 30, 2024, we have raised aggregate gross proceeds of $401.4 million to fund our operations, comprised primarily from proceeds received from the IPO, including proceeds from the underwriters partial exercise of their purchase option, our issuance of convertible promissory notes, SAFEs and private placements of our convertible preferred stock. In February 2021, we received a $30.0 million up-front payment from Merck for our two target programs. In addition, as of September 30, 2024, we have received $9.9 million related to reimbursable research services from Merck. As of September 30, 2024, we had cash, cash equivalents and investments of $199.6 million, and an accumulated deficit of $230.6 million. Based on our current operating plans, we expect our existing cash, cash equivalents and investments will be sufficient to fund our planned operating expenses and capital expenditure requirements at least through the end of 2026. Our total future capital requirements will depend on many factors and is subject to the risks and uncertainties set forth in the section titled "Risk Factors."

Future Funding Requirements

We expect our expenses and capital requirements to increase significantly in connection with our ongoing activities, particularly as we advance our lead product candidates and other development programs, in addition to the costs associated with operating as a public company. Accordingly, beyond the net proceeds raised in the IPO (including the partial exercise of the underwriters' option to purchase additional shares of common stock), we will continue to require substantial additional funding to support our continuing operations.

Our future capital requirements will depend on many factors, including:

- the initiation, type, number, scope, results, costs and timing of, our ongoing and planned clinical trials of AlloNK and preclinical studies and initiation of clinical trials for future product candidates, including feedback received from regulatory authorities;
- the costs and timing of manufacturing for our product candidates, including the costs and timing of maintaining our own manufacturing facility, and commercial scale manufacturing if any product candidate is approved;
- the potential expansion of our current development programs to seek new indications;
- the costs, timing and outcome of regulatory review of current or future product candidates;
- the costs of obtaining, maintaining and enforcing our patents and other intellectual property rights;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal controls over financial reporting;
- the costs associated with hiring additional personnel and consultants as our business grows, including additional executive officers and clinical development personnel;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements;
- the timing and amount of the milestone or other payments we must make to current and future collaborators and licensors;
- the costs and timing of establishing or securing sales and marketing capabilities if current or future product candidate is approved in a region where we choose to commercialize the product on our own;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products;
- patients' willingness to pay out-of-pocket for any approved products in the absence of coverage and/or adequate reimbursement from third-party payors; and
- costs associated with any products or technologies that we may in-license or acquire.

Until such time as we can generate substantial revenue from sales of our product candidates, if ever, we expect to finance our cash needs through public or private equity or debt financings or other capital sources, which may include strategic collaborations and other strategic arrangements with third parties. However, we may not be able to raise additional funds or enter into such other arrangements when needed or on favorable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaboration or licensing arrangements with third parties or other strategic transactions, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs, or product candidates or grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. If we are unable to raise additional funds or enter into such arrangements when needed, we could be forced to delay, limit, reduce or terminate our research and development programs or future commercialization efforts, or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves.

Cash Flows

Comparison of the Nine Months Ended September 30, 2024, and 2023

The following table sets forth a summary of the net cash flow activity for the nine months ended September 30, 2023, and 2024 (in thousands):

	NINE MONTHS ENDED SEPTEMBER 30,	
	2024	**2023**
Net cash (used in) provided by:		
Operating activities	$ (40,382)	$ (36,755)
Investing activities	(119,497)	(23,307)
Financing activities	162,256	23,429
Net increase (decrease) in cash	$ 2,377	$ (36,633)

Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2024, was $40.4 million, consisting primarily of our net loss incurred during the period of $49.3 million, offset by $8.9 million of non-cash charges. Non-cash charges consisted of $4.8 million in stock-based compensation expense, $3.6 million in change in fair value of SAFEs, and $1.8 million in depreciation and amortization expense, offset by $1.3 million of accretion of discounts on investments. Changes in operating assets and liabilities included a $1.1 million decrease in receivables, a $0.6 million increase in accounts payable, a $0.3 million increase in accrued expenses, and a $0.1 million change in other net balance sheet assets and liabilities, partially offset by a $2.1 million increase in prepaid expense and other current assets.

Net cash used in operating activities for the nine months ended September 30, 2023, was $36.8 million, consisting primarily of our net loss incurred during the period of $16.7 million and $27.2 million of a net decrease in operating assets and liabilities, partially offset by $7.2 million of net non-cash charges. Non-cash charges consisted primarily of $5.7 million in stock-based compensation expense and $1.7 million in depreciation and amortization expense, offset by $0.2 million of accretion of discounts on short-term investments. The net change in operating assets and liabilities primarily related to a $25.2 million decrease in deferred revenue, a $3.0 million increase in receivables, a $1.1 million decrease in accrued expenses, partially offset by a $1.5 million increase in accounts payable, a $0.3 million decrease in prepaid expenses and other current assets, and a $0.3 million change in other net balance sheet assets and liabilities.

Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2024, was $119.5 million related to $161.3 million of purchases of investments and $0.6 million of purchases of property and equipment, partially offset by $42.4 million in maturities of short-term investments.

Net cash used in investing activities for the nine months ended September 30, 2023, was $23.3 million related to $34.7 million of purchases of short-term investments and $2.6 million of purchases of property and equipment, partially offset by $14.0 million in maturities of short-term investments.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2024, was $162.3 million related to net cash proceeds received from the IPO.

Net cash provided by financing activities for the nine months ended September 30, 2023, was $23.4 million related to SAFE proceeds received.

Contractual Obligations and Commitments

In addition to ongoing capital needs to fund our ongoing operations, our material cash requirements include the following contractual and other obligations.

We lease certain office space in San Diego, California, under a non-cancelable operating lease, with a term through December 2025 (the Executive Drive Lease). The Executive Drive Lease commenced on December 23, 2019, with a six-year initial term and includes aggregate monthly payments to the lessor of approximately $2.8 million. The Executive Drive Lease also provides for rent abatements and scheduled increases in base rent. In connection with the lease, we made a one-time cash security deposit in the amount of $0.4 million, of which $0.2 million was refunded in October 2021 and the remaining $0.2 million is refundable at the end of the lease term and is included in long-term assets in the balance sheets. The Executive Drive Lease includes a renewal option, which includes an option to renew for five additional years. We will not exercise the option and, as such, is not reflected as part of the right of use asset and associated lease liabilities.

In June 2021, we entered into a lease agreement for corporate office and laboratory space in San Diego, California (the Morehouse Lease), which represented a portion of a new facility that was under construction. The Morehouse Lease includes multiple, successive commencement dates. The office and laboratory space commenced in the second quarter of 2022 and the third quarter of 2022 for the cGMP manufacturing center. The Morehouse Lease has an initial term of 88 months and includes aggregate monthly payments to the lessor of approximately $23.2 million with a rent escalation clause, and a tenant improvement allowance of $12.3 million. We are also required to maintain a cash security deposit in the form of an unconditional and irrevocable letter of credit of $0.3 million which must remain in place until the termination of the lease and is considered a non-current asset as of September 30, 2024. These obligations are further described in Note 12 to our audited financial statements and Note 11 to our unaudited condensed financial statements appearing elsewhere in this this Quarterly Report.

In August 2022, we entered into a lease agreement to use designated laboratory and vivarium space in San Diego, California (the Explora Lease). The Explora Lease is accounted for as an operating lease and commenced in August 2022. The Explora Lease has an initial term of 36 months and includes aggregate monthly payments to the lessor of approximately $0.8 million with a rent escalation clause.

On July 22, 2022, we entered into a sublease (the Sublease Agreement) with Origis Operating Services, LLC, (the Sublessee), whereby we agreed to sublease to Sublessee all of the 13,405 rentable square feet of office space currently leased by us under the Executive Drive Lease. The sublease commenced on August 1, 2022, and has a term through December 31, 2025. The aggregate base rent is approximately $2.6 million commencing August 1, 2022. We record sublease income as a reduction of general and administrative expense. Upon execution of the Sublease Agreement, we received a cash security deposit of $0.1 million from the Sublessee which is recorded as other non-current liabilities in the balance sheets.

As of September 30, 2024, we have future remaining operating lease payments of $17.9 million relating to leases we have recognized in the condensed balance sheets, of which $1.0 million is payable before December 31, 2024.

Under our collaboration agreements, we have milestone payment obligations that are contingent upon the achievement of specified development, regulatory and commercial sales milestones and are required to make certain royalty payments in connection with the sale of products developed under the agreement (see Note 8 to our financial statements included elsewhere in this Quarterly Report). As of September 30, 2024, we are unable to estimate the timing or likelihood of achieving the milestones or making future product sales and, therefore, any related payments are not included in the table above.

We enter into contracts in the normal course of business for contract research services, contract manufacturing services, professional services and other services and products for operating purposes. These contracts generally provide for termination after a notice period, and, therefore, are cancelable contracts and not included in the table above.

Off-Balance Sheet Arrangements

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

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles (GAAP). The preparation of our financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, expenses, and the disclosure of our contingent liabilities in our 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 an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

There have been no significant changes to our critical accounting estimates from those described in Management's Discussion and Analysis of Financial Condition and Results of Operations - Critical Accounting Policies and Significant Estimates and Judgments and our audited financial statements as of and for the year ended December 31, 2023 as included in the Company's prospectus dated July 18, 2024 related to its IPO filed pursuant to Rule 424(b)(4) under the Securities Act of 1933.

Emerging Growth Company and Smaller Reporting Company Status

As an emerging growth company under the JOBS Act, we can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to use the extended transition period for complying with new or revised accounting standards and as a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates. However, we may elect to early adopt any new or revised accounting standards whenever such early adoption is permitted for non-public companies. We may take advantage of these exemptions up until the time that we are no longer an emerging growth company.

We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year following the fifth anniversary of the consummation of this offering, (ii) the last day of the fiscal year in which we have total annual gross revenue of at least $1.235 billion, (iii) the last day of the fiscal year in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year, or (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company as defined in Item 10 of Regulation S-K and are not required to provide the information otherwise required under this item.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated, as of the end of the period covered by this Quarterly Report, the effectiveness of our disclosure controls and procedures. Based on that evaluation, our principal executive officer and principal financial officer concluded that, as of the end of the period covered by this Quarterly Report, our disclosure controls and procedures were effective at the reasonable assurance level. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act are recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2024, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Part II. Other Information

Item 1. Legal Proceedings

From time to time, we may 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

You should carefully consider the risks and uncertainties described below, as well as the other information in this Quarterly Report on Form 10-Q and in our other public filings, including in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and in our condensed financial statements and the related notes appearing elsewhere in this Quarterly Report on Form 10-Q and in our other public filings, which could materially affect our business, financial condition or future results. The risks described below are not the only risks that we face. The occurrence of any of the following risks, or of additional risks and uncertainties not presently known to us or that we currently believe to be immaterial, could materially and adversely affect our business, financial condition, results of operations and prospects.

We may disclose changes to risk factors or additional risk factors from time to time in our future filings with the SEC.

Risk Factor Summary

Below is a summary of the principal risks and uncertainties that make an investment in our securities speculative or risky. Importantly, this summary does not address all of the risks that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks that we face, follows this summary, and should be carefully considered, together with other information in this Quarterly Report on Form 10-Q and our other filings with the SEC before making investment decisions regarding our securities. This summary is qualified in its entirety by that more complete discussion of such risks and uncertainties.

The following is a summary of the principal risks and uncertainties described in more detail in this Quarterly Report:

- We have a limited operating history, have not completed any clinical trials and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability.
- We will need to obtain substantial additional funding to complete the development and any commercialization of our current and any future product candidates, which may cause dilution to our stockholders. If we are unable to raise this capital when needed, we may be forced to delay, reduce or eliminate our research and development programs or other operations.
- Our approach to the development of NK cell-based product candidates is unproven, and we do not know whether we will be able to develop any products of commercial value, or if competing technological approaches will limit the commercial value of our product candidates or render our platform obsolete.
- Our product candidates are based on novel technologies, which makes it difficult to predict the time and cost of developing product candidates and obtaining regulatory approval for any product candidates that we develop.
- We are early in our development efforts and are substantially dependent on the success of our lead product candidate, AlloNK, which is in early clinical development. Although we have other product candidates in our pipeline being developed by our partners, all of our other internally developed product candidates are in the preclinical or discovery stage. If we are unable to advance our product candidates in clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.
- Current clinical data regarding the efficacy of NK cell therapies against autoimmune diseases are limited, raising uncertainties about the therapeutic benefits of treatments like AlloNK for conditions such as LN and other autoimmune diseases. Moreover, these therapies may not prove to be competitive compared to existing treatments for autoimmune diseases.
- Clinical trials are expensive, time-consuming, difficult to design and implement, and have an uncertain outcome. Further, we may encounter substantial delays in our clinical trials.

•Our product candidates may cause serious adverse events or undesirable side effects or have other properties that may delay or prevent regulatory approval, cause us to suspend or discontinue clinical trials, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

•Enrollment and retention of patients in clinical trials is an expensive and time-consuming process subject to various external factors beyond our control that may cause delays or complications.

•Results of any patient who receives our product candidate in an investigator initiated trial should not be viewed as representative of how the product candidate will perform in our clinical trials and may not be able to be used to establish safety or efficacy for regulatory approval.

•The affected populations for our product candidates may be smaller than we or third parties currently project, which may affect the addressable markets for our product candidates.

•Our collaboration agreements with Affimed N.V. (Affimed), GC Cell Corporation (GC Cell) and any future collaborations with third parties to develop or commercialize our product candidates, mean that our prospects with respect to the product candidates involved will depend in significant part on the success of those collaborations.

•The manufacture of cell therapy products is novel, complex and subject to multiple risks. We could experience manufacturing problems, and/or we could be required to or choose to modify our manufacturing processes, which could result in delays in the development or commercialization of our product candidates or otherwise harm our business.

•We currently significantly rely on GC Cell for the manufacturing of our product candidates. While we have built our own clinical manufacturing facility and may decide to build our own commercial-scale manufacturing facility, we may encounter delays, quality or other issues if and when we begin to use our manufacturing facility for supply, and will continue to rely on GC Cell at least partially for manufacturing of our product candidates in the near term.

•Our partial reliance on third parties for manufacturing increases the risk that supply of our product candidates may become limited or interrupted or may not be of satisfactory quality and quantity.

•We are dependent on third parties to acquire, ship and store our cord blood units, NK cell master cell banks and drug product lots, viral vectors, and master and working feeder cell banks, and any disruption, quality concerns, damage or loss would cause delays in replacement and our business could suffer.

•Our cell therapy products depend on the availability of reagents and specialized materials and equipment, including cord blood and viral vectors, which in each case are required to be acceptable to the FDA and comparable foreign regulatory authorities, and such reagents, materials, and equipment may not be available to us on acceptable terms or at all. We and our third-party manufacturers rely on third-party suppliers for various components, materials and equipment required for the manufacture of our product candidates, some of which are single-source products, and do not have supply arrangements for certain of these components.

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

•We depend substantially on intellectual property rights granted under our agreements with GC Cell. If we lose our existing licenses or are unable to acquire or license additional proprietary rights from third parties, we may not be able to continue developing our product candidates.

•We will need to expand our organization, and we may experience significant challenges in managing this growth as we build our capabilities, which could disrupt our operations.

•Our future success depends on our ability to retain our key personnel and to attract, retain and motivate qualified personnel.

•A significant portion of our total outstanding shares are eligible to be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

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

We have a limited operating history, have not completed any clinical trials and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability.

We are a clinical stage biopharmaceutical company with a limited operating history. We were incorporated in February 2019 and our operations to date have been limited to organizing and staffing our company, business planning, raising capital, licensing key intellectual property rights, conducting research and development of our product candidates ourselves and with collaborators, collaborating on scale-up of product candidate manufacturing, establishing cold chain delivery logistics and preparing for and conducting our ongoing and planned preclinical studies and clinical trials.

AlloNK, our lead product candidate, is in early clinical development and our other product candidates and programs are in preclinical development or discovery stages. We have not yet demonstrated an ability to successfully complete a clinical program, including large-scale, pivotal clinical trials, obtaining marketing approval, manufacturing product at a commercial scale, or arranging for a third party to do so on our behalf, or conducting sales and marketing activities necessary for successful product commercialization. This may make it difficult to evaluate the success of our business to date and assess our future viability.

We expect to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and the significant risk that product candidates will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval or become commercially viable. For the year ended December 31, 2023 and for the nine months ended September 30, 2024, our net losses were $28.7 million and $49.3 million, respectively. As of September 30, 2024, we had an accumulated deficit of $230.6 million. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations.

We expect to continue to incur significant expenses and additional operating losses for the foreseeable future as we seek to advance our product candidates through preclinical and clinical development, expand our research and development activities, develop new product candidates, complete clinical trials, seek regulatory approval and, if we receive regulatory approval, commercialize our products. Furthermore, the costs of advancing product candidates into each succeeding clinical phase tend to increase substantially over time. The total costs to advance any of our product candidates to marketing approval in even a single jurisdiction would be substantial. Because of the numerous risks and uncertainties associated with cell therapy product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to generate any revenue from the commercialization of any approved products or achieve or maintain profitability. Our expenses will also increase substantially as we operate as a public company and add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts.

Before we generate any revenue from product sales, each of our product candidates will require additional preclinical and/or clinical development, potential regulatory approval in multiple jurisdictions, manufacturing, building of a commercial organization, substantial investment and significant marketing efforts. Our expenses could increase beyond expectations if we are required by the FDA, the European Medicines Agency (EMA), the competent authorities of individual European Union (EU) Member States or comparable foreign regulatory authorities to perform preclinical studies and clinical trials in addition to those that we currently anticipate, and/or to modify any of our manufacturing processes or make other changes to our product candidates or development programs. As a result, we expect to continue to incur net losses and negative cash flows for the foreseeable future. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital.

As we continue to build our business, we expect our financial condition and operating results may fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any particular quarterly or annual period as indications of future operating performance. If we are unable to develop and commercialize one or more of our product candidates either alone or with collaborators, or if revenues from any product candidate that receives marketing approval are insufficient, we will not achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability. If we are unable to achieve and then maintain profitability, the value of our securities will be adversely affected.

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

The development of biopharmaceutical product candidates is capital-intensive. We expect to spend substantial amounts to advance our product candidates into clinical development and to complete the clinical development of, seek regulatory approvals for and commercialize our product candidates, if approved. We will require additional capital, which we may raise through public or private equity or debt financings or other capital sources, which may include strategic collaborations and other strategic arrangements with third parties, to enable us to complete the development and potential commercialization of our product candidates. Furthermore, as a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative effect on our financial condition and our ability to pursue our business strategy. In addition, attempting to secure additional financing may divert the time and attention of our management from day-to-day activities and harm our development efforts. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, reduce or eliminate certain of our research and development programs.

Our operations have consumed significant amounts of cash since inception. As of September 30, 2024, our cash, cash equivalents and investments were $199.6 million. Based on our current cash, cash equivalents and investments, we estimate that our funds will be sufficient to enable us to fund our operating expenses and capital expenditure requirements at least through the end of 2026. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances could cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more than currently expected because of circumstances beyond our control. Because the length of time and activities associated with successful development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any marketing and commercialization activities.

Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the type, number, scope, progress, expansions, results, costs and timing of, discovery, preclinical studies and clinical trials of our current and future product candidates, including AlloNK (AB-101), AB-201 and AB-205;
- the costs and timing of manufacturing for our product candidates, including continuing to develop our own manufacturing capabilities;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA and comparable foreign regulatory authorities;
- the cost of obtaining, maintaining and protecting our intellectual property portfolio, including filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of establishing a sales, marketing and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval;
- the cost and timing of completion of commercial-scale manufacturing activities;
- the cost of making royalty, milestone or other payments under current and any future in-license agreements;
- the timing and amount of the milestone or other payments made to us under our current or any future collaboration agreements;
- costs associated with growing our workforce and retaining and motivating our employees;
- the initiation, progress, timing and results of our commercialization of our product candidates, if approved for commercial sale;
- costs associated with any products or technologies that we may in-license or acquire;
- the costs associated with being a public company; and
- our implementation of additional internal systems and infrastructure, including operational, financial and management information systems.

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. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of common stock. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Risks Related to the Discovery and Development of our Product Candidates

Our approach to the development of NK cell-based product candidates is unproven, and we do not know whether we will be able to develop any products of commercial value, or if competing technological approaches will limit the commercial value of our product candidates or render our platform obsolete.

Our success depends on our ability to develop, obtain regulatory approval for and commercialize our product candidates utilizing our NK cell therapy platform, including manufacturing capabilities, which leverages relatively novel technologies. While we have had favorable preclinical and early clinical study results based on our platform, we are early in our development efforts and may not succeed in demonstrating efficacy and safety for any product candidates in clinical trials or in obtaining marketing approval thereafter. Our understanding of NK cell biology is continuously evolving and this is particularly true in relation to autoimmune diseases where there is limited clinical data available. In particular, our approach in developing treatments for autoimmune diseases with NK cell-based therapies is novel and we have limited experience in doing so as our resources and processes have historically been focused on the development of NK cell-based therapies for cancer. We may also experience timeline delays or serious adverse events, and our product candidates may never become commercialized. All of our product candidates will require significant additional clinical and non-clinical development, review and approval by the FDA or comparable foreign regulatory authorities in one or more jurisdictions, substantial investment, and significant marketing efforts before they can be successfully commercialized. Our methodology and novel approach to cellular therapy may be unsuccessful in identifying additional product candidates, and any product candidates based on our platform may be shown to have harmful side effects or may have other characteristics that may necessitate additional clinical testing, or make the product candidates unmarketable or unlikely to receive marketing approval. Further, because all of our product candidates and development programs are based on our NK cell therapy platform, adverse developments with respect to one of our programs may have a significant adverse impact on the actual or perceived likelihood of success and value of our other programs. For example, if our clinical trials of AlloNK encounter safety, efficacy or manufacturing problems, development delays, regulatory issues or other problems, our development plans for our other product candidates in our pipeline could be significantly impaired.

The FDA has cautioned consumers about potential safety risks associated with T-cell therapies. The FDA has approved only a few cell-based therapies for commercialization and to our knowledge, no NK cell-based therapy has been approved for commercial use by any regulatory authority. Additionally, human primary cells are subject to donor-to-donor variability, which can make standardization more difficult. Understanding and addressing variability in the quality of a donor's cells, could ultimately affect our ability to produce product in a reliable and consistent manner and treat certain patients. As a result, the development and commercialization pathway for our product candidates may be subject to increased uncertainty, as compared to the pathway for new conventional drugs.

In addition, the biopharmaceutical industry is characterized by rapidly advancing technologies. Our future success will depend in part on our ability to maintain a competitive position with our NK cell-based approach. If we fail to stay at the forefront of technological change in utilizing our platform to create and develop product candidates, we may be unable to compete effectively. Our competitors may render our approach obsolete, or limit the commercial value of our product candidates, by advances in existing technological approaches or the development of new or different approaches, potentially eliminating the advantages in our manufacturing process that we believe we derive from our platform. By contrast, adverse developments with respect to other companies that attempt to use a similar approach to our approach may adversely impact the actual or perceived value of our platform and potential of our product candidates.

There is currently no cell therapy approved in the United States or elsewhere in the world for the treatment of any autoimmune disease, and our research and development activities related to AlloNK for treatment of autoimmune diseases, such as LN, may never lead to an approved product.

We are evaluating AlloNK in combination with B-cell targeted monoclonal antibodies (mAbs) to treat autoimmune diseases, such as LN. There is currently no cell therapy approved in the United States or elsewhere in the world for the treatment of any autoimmune disease. We cannot be certain that our approach will lead to the development of an approvable or marketable product. We may not succeed in demonstrating safety and efficacy of AlloNK in combination with B-cell targeted mAbs for the treatment of autoimmune diseases in our ongoing or anticipated clinical trials or in larger-scale clinical trials. Advancing AlloNK in development creates significant challenges for us, including:

- obtaining marketing approval, as the FDA and other comparable foreign regulatory authorities have yet to approve a cell therapy for the treatment of any autoimmune disease;
- if AlloNK in combination with a B-cell targeted mAb is approved, educating medical personnel regarding the potential efficacy and safety benefits, as well as the challenges, of incorporating our product into their clinical practice; and
- establishing the sales and marketing capabilities upon obtaining any marketing approvals to gain market acceptance.

Our product candidates are based on novel technologies, which makes it difficult to predict the time and cost of developing product candidates and obtaining regulatory approval for any product candidates that we develop.

The clinical trial requirements of the FDA and comparable foreign regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for product candidates such as ours can be more expensive and take longer than for other, better known, or more extensively studied pharmaceutical or other product candidates.

Regulatory requirements in the United States and in other countries governing cell therapy products are evolving and the FDA or comparable foreign regulatory authorities may change the requirements, or identify different regulatory pathways, for approval for any of our product candidates. For example, within the FDA, the Center for Biologics Evaluation and Research (CBER) restructured and created a new Office of Tissues and Advanced Therapies to better align its oversight activities with FDA Centers for Drugs and Medical Devices. It is possible that over time new or different divisions may be established or be granted the responsibility for regulating cell therapy products, including NK cell-based products, such as ours. As a result, we may be required to change our regulatory strategy or to modify our applications for regulatory approval, which could delay and impair our ability to complete the preclinical and clinical development and manufacture of, and obtain regulatory approval for, our product candidates. Changes in FDA or comparable foreign regulatory authorities and advisory groups, or any new requirements or guidelines they promulgate, may lengthen the regulatory review process, require us to perform additional studies, increase our development and manufacturing costs, lead to changes in regulatory pathways, positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions.

We have concentrated our research and development efforts on utilizing NK cell-based therapies. To date, the FDA has approved only a few cell-based therapies for commercialization and no NK cell-based therapy has been approved for commercial use by any regulatory authority. The processes and requirements imposed by the FDA or comparable foreign regulatory authorities may cause delays and additional costs in obtaining approvals for marketing authorization for our product candidates. Because our platform is novel, and cell-based therapies are relatively new, especially as potential treatments for autoimmune diseases, regulatory authorities may lack experience in evaluating product candidates like our product candidates. This novelty may lengthen the regulatory review process, including the time it takes for the FDA or comparable foreign regulatory authorities to review our Investigational New Drug applications (INDs) or comparable foreign applications if and when submitted, increase our development costs and delay or prevent commercialization of our product candidates. Additionally, advancing novel immune-oncology therapies creates significant challenges for us, including:

- educating medical personnel regarding the potential side-effect profile of our product candidates and, as the clinical program progresses, on observed side effects with the product candidates;
- training medical personnel;
- enrolling sufficient numbers of patients in clinical trials; and
- continuing to develop a manufacturing process to support the clinical testing of our product candidates.

We must be able to overcome these challenges in order for us to develop, commercialize and manufacture our product candidates.

As we advance our product candidates, we will be required to consult with the FDA and comparable foreign regulatory authorities and our product candidates will likely be reviewed by an FDA advisory committee. We also must comply with applicable requirements, and if we fail to do so, we may be required to delay or discontinue development of our product candidates. Delays or unexpected costs in obtaining, or the failure to obtain, the regulatory approval necessary to bring a potential product to market could impair our ability to generate sufficient product revenues to maintain our business.

In addition, either advances or adverse developments in preclinical studies or clinical trials conducted by others in the field of cell therapy products, and cellular immunotherapies in particular, may cause the FDA and comparable foreign regulatory authorities to revise the requirements for approval of any product candidates we may develop, and may otherwise negatively affect our ability to develop and commercialize our product candidates. The regulatory review committees and advisory groups described above and the new guidelines they promulgate may lengthen the regulatory review process, require us to perform additional preclinical studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these treatment candidates, or lead to significant post-approval limitations or restrictions. As we advance our research programs and develop future product candidates, we will be required to consult with these regulatory and advisory groups and to comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of any product candidates we identify and develop.

We are early in our development efforts and are substantially dependent on the success of our lead product candidate, AlloNK, which is in early clinical development. Although we have other product candidates in our pipeline being developed by our partners, all of our other internally developed product candidates are in the preclinical or discovery stage. If we are unable to advance our product candidates in clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

We are in the early stages of our development efforts and are substantially dependent on the success of our lead product candidate, AlloNK, which is in early clinical development. Although we have other product candidates in our pipeline being developed by our partners, all of our other internally developed product candidates are still in the preclinical or discovery stages. We have not yet completed any clinical trials for any product candidate. We will need to progress AlloNK through our recently initiated trial and progress our other early product candidates through preclinical studies and submit INDs to the FDA or comparable foreign regulatory applications to applicable foreign regulatory authorities prior to initiating clinical trials.

Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates. The success of our product candidates will depend on several factors, including the following:

- successful enrollment in, and completion of, clinical trials with favorable results;
- completion of preclinical studies with favorable results;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- allowance to proceed with clinical trials under INDs by the FDA or under similar regulatory submissions by applicable foreign regulatory authorities for the conduct of clinical trials of our product candidates and our proposed design of future clinical trials;
- demonstrating the safety and efficacy of our product candidates to the satisfaction of the FDA and other applicable foreign regulatory authorities;
- receipt of regulatory approvals from applicable regulatory authorities, including new drug applications (NDAs) from the FDA and approvals from comparable foreign regulatory authorities and maintaining such approvals;
- making arrangements with third-party manufacturers, or manufacturing sufficient quantities of product candidates for clinical and commercial use using our own facilities;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- establishing and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates;
- acceptance of any products we develop and their benefits and uses, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;

•obtaining and maintaining healthcare coverage and adequate reimbursement from third-party payors;

•maintaining an acceptable safety profile of our products following approval; and

•building and maintaining an organization of people who can successfully develop our product candidates.

We have not yet succeeded and may not succeed in demonstrating efficacy and safety for any product candidates in clinical trials or in obtaining marketing approval thereafter. Given our early stage of development, it will take several years before we can demonstrate the safety and efficacy of a product candidate sufficient to warrant approval for commercialization, if we can do so at all. If we are unable to develop, or obtain marketing approval for, or, if approved, successfully commercialize our product candidates, we may not be able to generate sufficient revenue to continue our business.

Current clinical data regarding the efficacy of NK cell therapies against autoimmune diseases are limited, raising uncertainties about the therapeutic benefits of treatments like AlloNK for conditions such as LN and other autoimmune diseases. Moreover, these therapies may not prove to be competitive compared to existing treatments for autoimmune diseases.

While we believe in the potential of our allogeneic NK cell-based product candidate, AlloNK, in combination with a B-cell targeted mAb may have a clinical benefit for autoimmune diseases, such as LN, the use of NK cell-based therapies in combination with mAbs represents a novel approach for the treatment of autoimmune disease, and is supported by limited clinical data. To date, the FDA has not approved any cell therapies for autoimmune diseases, adding to the uncertainty surrounding our ongoing Phase 1/1b clinical trial of AlloNK in combination with rituximab or obinutuzumab in patients with SLE with or without LN who previously failed treatment and potential future developments for autoimmune diseases.

Our belief that AlloNK may be effective as a treatment for autoimmune disease is based on our interpretation of positive clinical data from academic groups using autologous auto-CAR-T in a limited autoimmune disease patient cohort, as well as our own preliminary data from our ongoing Phase 1/2 clinical trial of AlloNK in combination with rituximab in patients with relapsed or refractory B-NHL, which demonstrated complete responses in B-NHL patients as measured by imaging of tumor lesions. We have made certain assumptions regarding the approach responsible for the preliminary activity shown in the reported studies and how that approach and our own preliminary data from our Phase 1/2 clinical trial in patients with aggressive B-NHL will translate to patients with autoimmune diseases, such as LN, which may not be correct.

We cannot be certain whether AlloNK in combination with a B-cell targeted mAb will effectively treat LN, other manifestations of SLE, or any autoimmune disease for that matter, nor can we guarantee its competitiveness against auto-CAR-T. Additionally, we face competition from numerous cell therapy companies with strong oncology backgrounds, all pursuing development programs in autoimmune diseases, which could hinder our efforts to successfully develop and commercialize AlloNK in combination with a B-cell targeted mAb.

If our clinical trials reveal insufficient activity of AlloNK in combination with a B-cell targeted mAb against autoimmune diseases, such as LN, encounter delays in advancing AlloNK through clinical development, or if we struggle to compete with other companies in developing and marketing AlloNK in combination with a B-cell targeted mAb, it would significantly impact the commercial prospects of AlloNK, as well as our business, financial condition and growth outlook.

We are developing, and in the future may develop, other product candidates in combination with other therapies, which exposes us to additional risks.

We are developing AlloNK for combination with approved B-cell targeted mAbs. For example, our ongoing Phase 1/2 clinical study is administering AlloNK in combination with rituximab in patients with relapsed or refractory B-NHL. Beyond rituximab and other anti-CD20 mAbs, we have already conducted numerous preclinical studies in which we have shown cytotoxic activity of AlloNK in combination with other approved B-cell targeted mAb therapies, such as anti-CD19 and anti-CD38 mAbs. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or comparable foreign regulatory authorities could revoke approval of the therapy used in combination with our product candidate. There is also a risk that safety, efficacy, manufacturing or supply issues could arise with these other existing therapies. For example, the other therapies may lead to toxicities that are improperly attributed to our product candidates or the combination of our product candidates with other therapies may result in negative or inconclusive results that the product candidate or other therapy does not produce when used alone or in combination with a different therapy. This could result in our own products being removed from the market or being less successful commercially. Additionally, the results observed in combinations of any of our product candidates with another therapy may not be predictive of future results of combinations of our product candidates in other combinations or indications.

We may also evaluate our future product candidates in combination with one or more other therapies that have not yet been approved for marketing by the FDA or comparable foreign regulatory authorities. We will not be able to market any product candidate we develop in combination with any such unapproved therapies that do not ultimately obtain marketing approval.

If the FDA or comparable foreign regulatory authorities do not approve these other drugs or revoke their approval of, or if safety, efficacy, manufacturing or supply issues arise with, the drugs we choose to evaluate in combination with any product candidate we develop, we may be unable to obtain approval.

Interim, topline and preliminary data from our preclinical studies or clinical trials that we announce or publish from time to time may not be predictive of future results and may change as more patient data become available and are subject to audit and verification procedures, which could result in material changes to the final data.

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

Further, others, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and 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, product candidate or our business. If the interim, topline or preliminary data that we report differ from actual results, or if others including comparable foreign regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Moreover, results from previous preclinical studies or clinical trials are not necessarily predictive of future clinical trial results, and interim results of a clinical trial are not necessarily indicative of final results. Our product candidates may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies of our product candidates or having successfully advanced through initial clinical trials.

Clinical trials are expensive, time-consuming, difficult to design and implement, and have an uncertain outcome. Further, we may encounter substantial delays in our clinical trials.

The clinical trials and manufacturing of our product candidates are subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and market our product candidates. Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication. In particular, because our product candidates are subject to regulation as biological drug products, we will need to demonstrate that they are safe, pure and potent for use in their target indications. Each product candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use.

Clinical testing is expensive and takes many years to complete, and is subject to uncertainty. Our planned clinical trials may not be conducted as planned or completed on schedule, if at all. Delays and failures can occur at any time during the clinical trial process. Even if our future clinical trials are completed as planned, their results may not support the safety and effectiveness of our product candidates for their targeted indications or support continued clinical development of such product candidates. Our future clinical trial results may not be successful.

In addition, even if our planned trials are successfully completed, the FDA or comparable foreign regulatory authorities may not interpret the results as we do, and more trials could be required before we submit our product candidates for approval. To the extent that the results of the trials are not satisfactory to the FDA or comparable foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

To date, we have not completed any clinical trials required for the approval of our product candidates. We may experience delays in conducting any clinical trials, and we do not know whether our clinical trials will begin on time, will need to be redesigned, will recruit and enroll patients on time or have data readouts or be completed on schedule, or at all. Events that may prevent successful or timely commencement, readouts, and completion of clinical development and preclinical studies include:

- inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation of clinical trials;
- delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for advanced clinical trials, or failure to do so;
- delays in reaching agreement with the FDA, or other comparable foreign regulatory authorities as to the design or implementation of our clinical trials, or failure to do so;
- delays in or failure to obtain regulatory approval to commence a clinical trial;
- delays in or failure to reach an agreement on acceptable terms with clinical trial sites or prospective contract research organizations (CROs) the terms of which can be subject to extensive negotiation and may vary significantly among different clinical trial sites;
- delays in or failure to obtain institutional review board (IRB) approval or positive ethics committee opinion at each site;
- delays in or failure to recruit suitable patients to participate in a clinical trial;
- delays in or failure to develop and validate the companion diagnostic to be used in a clinical trial, if applicable;
- delays in or failure to have patients complete a clinical trial or return for post-treatment follow-up;
- clinical sites, CROs or other third parties deviating from trial protocol or dropping out of a trial;
- failure to perform in accordance with the FDA's good clinical practice (GCP) requirements, or applicable regulatory guidelines in other countries;
- the serious, life-threatening diseases of the patients enrolled in our clinical trials, who may die or suffer adverse medical events during the course of the trials for reasons that may not be related to our product candidates;
- failure in addressing patient safety concerns that arise during the course of a trial, including occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- failure to add a sufficient number of clinical trial sites; or
- failure to manufacture sufficient quantities of product candidate for use in clinical trials.
- We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates or significantly increase the cost of such trials, including:
- we may experience changes in regulatory requirements or guidance, or receive feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

•we or our investigators might have to suspend or terminate clinical trials of our product candidates for various reasons, including non-compliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics, a finding that the participants are being exposed to unacceptable health risks;

•adverse events suffered by clinical trial participants that may ultimately be determined to be unrelated to our product candidates;

•the cost of clinical trials of our product candidates may be greater than we anticipate and we may elect not to cover the costs;

•the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;

•regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; and

•any future collaborators that conduct clinical trials may face any of the above issues, and may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

•incur unplanned costs;

•be delayed in obtaining marketing approval for our product candidates or not obtain marketing approval at all;

•obtain marketing approval in some countries and not in others;

•obtain marketing approval for indications or patient populations that are not as broad as intended or desired;

•obtain marketing approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;

•be subject to additional post-marketing testing requirements; or

•have the product removed from the market after obtaining marketing approval.

We could encounter delays if a clinical trial is suspended or terminated by us, by the institutional review boards (IRBs) or ethics committees of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board (DSMB) for such trial or by the FDA or comparable foreign regulatory authorities. These authorities may impose such a suspension or termination 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 comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Our lead product candidate, AlloNK, will require extensive clinical testing before we are prepared to submit a biologics license application (BLA) or marketing authorization application (MAA) for regulatory approval. We cannot predict with any certainty if or when we might complete the clinical development for our product candidates and submit a BLA or MAA for regulatory approval of any of our product candidates or whether any such BLA or MAA will be approved. We may also seek feedback from the FDA, or other comparable foreign regulatory authorities on our clinical development program, and the FDA or such other comparable foreign regulatory authorities may not provide such feedback on a timely basis, or such feedback may not be favorable, which could further delay our development programs.

We also cannot predict with any certainty whether or when we might complete a given clinical trial. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our product candidates could be harmed, and our ability to generate revenues from our product candidates may be delayed. In addition, any delays in our clinical trials could increase our costs, slow down the development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and results of operations. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Our product candidates may cause serious adverse events or undesirable side effects or have other properties that may delay or prevent regulatory approval, cause us to suspend or discontinue clinical trials, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

We have not yet completed any human clinical trials of our product candidates. Undesirable side effects that may be caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label than anticipated or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics.

While we believe the interim data reported to date from our Phase 1/2 B-NHL clinical trial indicate that NK cell-based therapies may have the potential to be better tolerated as compared to T cell based therapies due to biologic differences between these cell types there remains a risk of serious adverse events. In addition, historically, clinical trials using NK cell therapies in human subjects have been well-tolerated; however, it is possible that adverse events, including CRS, neurotoxicity or graft-versus-host disease will occur in human subjects during clinical trials.

Furthermore, clinical trial results could reveal an unacceptable severity or incidence of other adverse events, including heart and lung problems or life-threatening infections. Any such findings could cause delays in completion or cancellation of clinical programs. Furthermore, in some instances, the diseases we may be seeking to treat may be less serious than the later stage cancers traditionally being treated with cell therapies or other immunotherapy products. Therefore, we believe the FDA and comparable foreign regulatory authorities may apply a different risk-benefit threshold to our product candidates pursuing autoimmune indications such that any potential harmful side effects that may outweigh the benefits of such product candidates would require us to cease clinical trials or abandon or limit our development of these product candidates or would cause the FDA or comparable foreign regulatory authorities to deny marketing applications for these product candidates. We believe for the FDA and other regulatory authorities may weigh adverse events in the autoimmune patient populations being pursued with cell-based therapies, such as in the LN patients in our Phase 1/1b clinical trials, may be lower than it is in oncology, and the risks of negative impact from these toxicities may therefore be higher for our autoimmune programs than for our oncology programs or the oncology programs of others.

If unacceptable side effects or deaths arise in the development of our product candidates, we, the FDA, the IRBs or ethics committees at the institutions in which our studies are conducted, DSMB or comparable foreign regulatory authorities could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. For example, the FDA put our Phase 1/2 clinical trial of AlloNK in combination with rituximab in patients with relapsed or refractory B-NHL on clinical hold in April 2021 due to a patient death and lifted the clinical hold in June 2021 after our investigation and amendments to the clinical trial protocol. Although there was no definitive cause of death, the autopsy findings included widespread metastatic disease and cardiovascular disease, and concluded that the death was possibly due to cardiac arrhythmia. The principal investigator determined that this serious adverse event was not related to AlloNK. We may observe undesirable side effects and we may not be able to complete a clinical trial for AlloNK or any of our other product candidates without further delays or at all. Further undesirable side effects, dose-limiting toxicity events, or deaths in clinical trials with our product candidates may cause the FDA or comparable foreign regulatory authorities to place a clinical hold on the associated clinical trials, to require additional studies, dose de-escalation, or additional protocol amendments, or otherwise to delay or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect site initiation, patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly.

We study our product candidates in patient populations with significant comorbidities, and these patients may also receive treatment with cytotoxic lymphodepletion agents, cytokines, monoclonal antibodies and/or other treatments that may result in deaths or serious adverse or unacceptable side effects and require us to abandon or limit our clinical development activities.

Patients treated with our product candidates in clinical trials may also receive treatment with cytotoxic lymphodepletion agents, cytokines, monoclonal antibodies and/or other treatments, and may therefore experience side effects or adverse events, including death, that are unrelated to our product candidates. While these side effects or adverse events may be unrelated to our product candidates, they may still affect the success of our clinical studies. The inclusion of seriously ill patients in our autoimmune clinical trials, and critically ill patients in our oncology clinical trials may result in deaths or other adverse medical events due to underlying disease or to other therapies or medications that such patients may receive. Any of these events could prevent us from advancing our product candidates through clinical development, and from obtaining regulatory approval, and would impair our ability to commercialize our product candidates. Any inability to advance our existing product candidates or any other product candidate through clinical development would have a material adverse effect on our business, and the value of our common stock would decline.

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process subject to various external factors beyond our control that may cause delays or complications.

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 its conclusion. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials to such trials' conclusion as required by the FDA or other comparable foreign regulatory authorities. We may experience difficulty in patient enrollment in our clinical trials for a number of reasons. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size and nature of the patient population required for analysis of the trial's endpoints;
- the proximity of patients to study sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including new products that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient consents for participation in our clinical trials; and
- the risk that patients enrolled in clinical trials will not remain in the trial through the completion of evaluation.

Competing with numerous ongoing trials and established therapies poses a challenge in recruiting patients. Our clinical trials may also compete with other clinical trials of product candidates that are in a similar cellular immunotherapy area as our product candidates, and this competition could 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. Additionally, for our ongoing Phase 1/1b clinical trial of AlloNK in combination with rituximab or obinutuzumab in patients with SLE with or without LN who previously failed treatment, and any future AlloNK clinical trials for the treatment of other autoimmune diseases, the number of qualified clinical investigators is limited, so we may 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 site. Recent announcements of clinical trial plans by various cell therapy companies targeting autoimmune diseases, including LN, could intensify future competition for investigators and patients. Failure to enroll a sufficient number of patients promptly could lead to delays or failure in completing our trials, hindering the development and commercialization of our product candidates within certain patient subgroups or altogether.

Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all.

In order to obtain FDA or comparable foreign regulatory authority approval to market a new biological product we must demonstrate proof of safety, purity and potency, or efficacy, in humans. To meet these requirements, we will have to conduct adequate and well-controlled clinical trials. AlloNK is our only product candidate to enter clinical development. Before we can commence clinical trials for additional product candidates, we must complete extensive preclinical testing and studies that support our planned INDs in the United States and comparable applications outside the United States.

We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA or comparable foreign regulatory authorities will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our programs. As a result, we may not submit INDs or similar applications for our preclinical programs within our anticipated timelines, if at all, and submission of INDs or similar applications may not result in the FDA or comparable foreign regulatory authorities allowing clinical trials to begin.

Conducting preclinical testing is a lengthy, time-consuming and expensive process. The length of time may vary substantially according to the type, complexity and novelty of the program, and often can be several years or more per program. Any delays in preclinical testing and studies conducted by us or potential future partners may cause us to incur additional operating expenses. The commencement and rate of completion of preclinical studies for a product candidate may be delayed by many factors, including, for example:

- inability to generate sufficient preclinical or other in vivo or in vitro data to support the initiation of clinical trials;
- delays in reaching a consensus with regulatory authorities on study design; and

•the FDA (or comparable foreign regulatory authorities) not allowing us to rely on previous findings of safety and efficacy for other similar but approved products and published scientific literature.

Moreover, because standards for pre-clinical assessment are evolving and may change rapidly, even if we reach an agreement with the FDA on a pre-IND proposal, the FDA may not accept the IND submissions as presented, in which the clinical trial timeline could be delayed.

We may not identify or discover other product candidates and may fail to capitalize on programs or product candidates that may present a greater commercial opportunity or for which there is a greater likelihood of success.

Our business depends upon our ability to identify, develop and commercialize product candidates. A key element of our strategy is to discover and develop additional product candidates based upon our NK cell therapy platform. We are seeking to do so through our collaborations with GC Cell and Affimed, and may also explore additional strategic collaborations for the discovery of new product candidates. Research programs to identify product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. In addition, targets for different autoimmune diseases or cancers may require changes to our manufacturing processes, which may slow down development of or make it impossible to manufacture our product candidates. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following:

•the research methodology or technology platform used may not be successful in identifying potential product candidates;

•competitors may develop alternatives that render our product candidates obsolete or less attractive;

•we may choose to cease development if we determine that clinical results do not show promise;

•product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;

•a product candidate may be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria; and

•a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

Because we have limited resources, we must choose to pursue and fund the development of specific types of treatment, select certain other therapies to test in combination with our product candidates or treatment for a specific type of autoimmune disease or cancer, and we may forego or delay pursuit of opportunities with certain programs or product candidates or combinations or for indications that later prove to have greater commercial potential. Our estimates regarding the potential market for our product candidates could be inaccurate, and if we do not accurately evaluate the commercial potential for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic collaboration, licensing or other arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Alternatively, we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

If any of these events occur, we may be forced to abandon or delay our development efforts with respect to a particular product candidate or fail to develop a potentially successful product candidate.

Results of any patient who receives our product candidate in an IIT should not be viewed as representative of how the product candidate will perform in our clinical trials and may not be able to be used to establish safety or efficacy for regulatory approval.

Before seeking regulatory approval for any of our product candidates, we must demonstrate statistically significant evidence of both safety and effectiveness in well-controlled clinical trials. However, we do not control the design, administration, or timing of investigator-initiated trials (IITs). We rely on investigators and physicians to ensure their compliance with clinical and regulatory requirements when using our product candidates for these trials. Failure to comply could expose us to liability.

While IITs may provide valuable insights, their results cannot be used to establish safety or efficacy for regulatory approval. In fact, they may identify concerns that could impact our findings or ongoing trials, potentially delaying or jeopardizing regulatory approval from the FDA or other regulatory bodies. If results from IITs differ from our sponsored trials or raise concerns, regulatory authorities may question our sponsored trial results and subject them to greater scrutiny. This could result in the need for additional clinical data, delaying clinical development and approval of our product candidates.

Moreover, the patient population in such trials is at high risk for serious adverse events. If these events are attributed to our product candidates, it could negatively impact their safety profile, leading to delays or failure in obtaining regulatory approval or successfully commercializing our drug candidates. Additionally, our supply capabilities may limit patient enrollment in these trials. We may need to restructure or pause supply to enroll sufficient patients in our sponsored trials, potentially leading to adverse publicity or other disruptions.

In summary, while IITs offer valuable insights, they also pose regulatory and operational challenges that could impact our ability to bring our product candidates to market.

The affected populations for our product candidates may be smaller than we or third parties currently project, which may affect the addressable markets for our product candidates.

We select the targets for development of our product candidates based on a number of factors, including the estimated patient populations where we believe there is a meaningful addressable market opportunity. However, our projections of the number of people who have the diseases we are seeking to treat, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are estimates based on our knowledge and understanding of these diseases. The total addressable market opportunity for our product candidates will ultimately depend upon a number of factors, including the diagnosis and treatment criteria included in the final label, if approved for sale in specified indications, acceptance by the medical community, patient access, alternative therapies and product pricing and reimbursement. For example, we intend to prioritize evaluation and seeking approval for AlloNK in combination with a B-cell targeted mAb in autoimmune diseases. Incidence and prevalence estimates are frequently based on information and assumptions that are not exact and may not be appropriate, and the methodology is forward-looking and speculative. The process we have used in developing an estimated incidence and prevalence range for the indications we are targeting has involved collating limited data from multiple sources..

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

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspectional operations, any resurgence of the virus or emergence of new variants may lead to further inspectional or administrative delays. If a prolonged government shutdown occurs or other public health crisis were to occur that prevented the FDA or comparable foreign regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or comparable foreign regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Risks Related to Manufacturing and Our Reliance on Third Parties

If third parties that we rely on to conduct clinical trials do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain marketing approval for or commercialize our product candidates.

We do not independently conduct clinical trials. We rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct or otherwise support clinical trials for our product candidates. In addition, for AB-201 and AB-205, our partner GC Cell will be engaging in initial clinical development outside our licensed territories to generate initial proof of concept data. We rely heavily on these parties for execution of clinical trials for our product candidates and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on CROs and other third parties will not relieve us of our regulatory responsibilities. For any violations of laws and regulations during the conduct of our clinical trials, we could be subject to untitled letters, warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

We and the third parties on which we rely for clinical trials are required to comply with regulations and requirements, including GCP for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial patients are adequately informed of the potential risks of participating in clinical trials and their rights are protected. These regulations are enforced by the FDA, the competent authorities of the EU Member States, and comparable foreign regulatory authorities for any drugs in clinical development. The FDA and competent authorities of EU Member States enforces GCP requirements through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we or these third parties fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA or comparable foreign regulatory authorities will determine that any of our future clinical trials will comply with GCP. In addition, our clinical trials must be conducted with product candidates produced under current Good Manufacturing Practices (cGMP) regulations. Our failure or the failure of these third parties to comply with these regulations may require us to repeat clinical trials, which would delay the marketing approval process and could also subject us to enforcement action. We also are required to register certain ongoing clinical trials and provide certain information, including information relating to the trial's protocol, on a government-sponsored database, ClinicalTrials.gov, within specific timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Although we intend to design the clinical trials for our product candidates, we will rely on third parties to conduct our clinical trials. As a result, many important aspects of our clinical development, including clinical trial conduct and timing, will be outside of our direct control. Our reliance on third parties to conduct future clinical trials will also result in less direct control over the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff.

Communicating with outside parties can also be challenging, potentially leading to mistakes, as well as difficulties in coordinating activities. Outside parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues;
- undergo changes in priorities or become financially distressed; or
- form relationships with other entities, some of which may be our competitors.

If third parties do not perform our clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, we would be unable to rely on clinical data collected by these third parties and may be required to repeat, extend the duration of, or increase the size of any clinical trials we conduct, which could significantly delay commercialization and require significantly greater expenditures.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms, or at all. If 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 are compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any clinical trials such third parties are associated with may be extended, delayed or terminated, and we may not be able to obtain marketing approval for or successfully commercialize our product candidates. As a result, we believe that our financial results and the commercial prospects for our product candidates in the subject indication would be harmed, our costs could increase and our ability to generate revenue could be delayed.

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

We may, from time to time, such as for our ongoing Phase 1/1b clinical trial for of AlloNK in combination with rituximab or obinutuzumab in patients with SLE with or without LN who previously failed treatment, establish partnerships in relation to our clinical trials, receiving advisory services and other support from third parties. Although we believe that these partnerships will enable us to accelerate the development of our product candidates and clinical trials, we cannot guarantee that such collaborations will be successful and, in the event they are not, we may lose our competitive advantage and/or incur additional costs.

Our collaboration agreements with Affimed, GC Cell and any future collaborations with third parties to develop or commercialize our product candidates, mean that our prospects with respect to the product candidates involved will depend in significant part on the success of those collaborations.

Our collaborations, including our collaborations with Affimed and GC Cell, and any future collaborations we may enter with third parties, could result in the following risks:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators could fail to conduct trials on the timeline we expect or otherwise fail to support our partnered trials;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- collaborators could encounter safety or efficacy problems, manufacturing problems, developmental delays, regulatory issues or other problems with our partnered trials;
- collaborators may not properly enforce, maintain or defend our intellectual property rights or may use our proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation, or other intellectual property proceedings;
- disputes may arise between a collaborator and us that cause the delay or termination of the research, development or commercialization of the product candidate, or that result in costly litigation or arbitration that diverts management attention and resources;
- if a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated; and
- collaboration agreements may restrict our right to independently pursue new product candidates.

In addition, if conflicts arise between our collaborators and us, our collaborators may act in a manner adverse to us and could limit our ability to implement our strategies. Future collaborators may develop, either alone or with others, products in related fields that are competitive with the products or potential products that are the subject of these collaborations. Competing products, either developed by the collaborators or to which the collaborators have rights, may result in the withdrawal of support for our product candidates. Our collaborators may preclude us from entering into collaborations with their competitors, fail to obtain timely regulatory approvals, terminate their agreements with us prematurely or fail to devote sufficient resources to the development and commercialization of products. Any of these developments could harm our product development efforts.

As a result, if we enter into collaboration agreements and strategic partnerships or license our intellectual property, products or businesses, such as our agreements with GC Cell and Affimed, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations, which could delay our timelines or otherwise adversely affect our business. Following a strategic transaction or license, we may not achieve the revenue or specific net income that justifies such transaction.

We may seek to form collaborations in the future with respect to our product candidates, but may not be able to do so, which may cause us to alter our development and commercialization plans.

The advancement of our product candidates and development programs and the potential commercialization of our current and future product candidates will require substantial additional cash to fund expenses. For some of our programs, we may seek to collaborate with pharmaceutical and biotechnology companies to develop and commercialize such product candidates, such as our collaborations with Affimed. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business.

We face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Whether we reach a definitive agreement for other collaborations will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the progress of our clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. Further, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for future product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view them as having the requisite potential to demonstrate safety and efficacy. Any delays in entering into new collaborations or strategic partnership agreements related to any product candidate we develop could delay the development and commercialization of our product candidates, which would harm our business prospects, financial condition and results of operations.

The manufacture of cell therapy products is novel, complex and subject to multiple risks. We could experience manufacturing problems, and/or we could be required to or choose to modify our manufacturing processes, which could result in delays in the development or commercialization of our product candidates or otherwise harm our business.

Our product candidates utilize primary human NK cells, and the process of manufacturing such product candidates is complex, highly regulated and subject to numerous risks. As a result of these complexities, manufacturing our cellular therapy product candidates is generally more complicated than traditional small-molecule chemical compounds or biologics. In addition, our cost of goods development is at an early stage. The actual cost to manufacture and process our product candidates could be greater than we expect and could materially and adversely affect the commercial viability of our product candidates. Moreover, the manufacturing processes for certain of our existing CAR-NK cell product candidates have not been tested at full scale.

Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our product candidates or in any of the manufacturing facilities in which products or other materials are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

We plan to make changes to our manufacturing processes for various reasons, such as to control costs, meet new or additional regulatory requirements, achieve scale, decrease processing time, increase manufacturing success rate, to facilitate the development of future product candidates or for other reasons, and we cannot be sure that even minor changes in these processes will not cause our current or future product candidates to perform differently and affect the results of our ongoing and planned clinical trials or the performance of the product once commercialized. Changes to our processes made during the course of clinical development will require us to amend our IND submission to the FDA to show the comparability of the product used in earlier clinical phases or at earlier portions of a trial to the product used in later clinical phases or later portions of the trial. Other changes to our manufacturing processes made before or after commercialization could require us to show the comparability of the resulting product to the product candidate used in the clinical trials using earlier processes. This could require us to collect additional nonclinical or clinical data from any modified process prior to obtaining marketing approval for the product candidate produced with such modified process. If such data are not ultimately comparable to that seen in the earlier trials or earlier in the same trial in terms of safety or efficacy, we may be required to make further changes to our processes and/or undertake additional clinical testing, either of which could significantly delay the clinical development or commercialization of the associated product candidate, which would materially adversely affect our business, financial condition, results of operations and growth prospects.

We may experience unforeseen events during, or as a result of, ramping up our manufacturing process that could result in delays in manufacturing sufficient quantities of our product candidates or otherwise harm our business.

We currently significantly rely on GC Cell for the manufacturing of our product candidates. While we have built our own clinical manufacturing facility and may decide to build our own commercial-scale manufacturing facility, we may encounter delays, quality or other issues if and when we begin to use our manufacturing facility for supply, and will continue to rely on GC Cell at least partially for manufacturing of our product candidates in the near term.

We currently significantly rely on GC Cell to manufacture our product candidates. If GC Cell were to breach their agreement with us or otherwise fail to perform for any reason, including due to the loss of key members of GC Cell's management or other key employees, we likely would experience delays while we identify and qualify a replacement manufacturer and we may be unable to do so on terms that are favorable to us, which may make it more difficult for us to develop our product candidates and compete effectively. We have built our own clinical manufacturing facility and may decide to build our own commercial-scale manufacturing facility, or may elect to contract with other third-party contract manufacturers. Our cGMP manufacturing center is currently fully functional pending FDA authorization to use product candidates manufactured at this facility to supply our clinical trials, but we may also encounter delays or quality or other issues as we begin to use our manufacturing facility or rely on other third-party contract manufacturers given the complexity of manufacturing cell therapies. In addition, if we cannot obtain FDA authorization to utilize product candidates manufactured from our cGMP manufacturing center on a timely basis or at all, we could experience supply constraints that could delay our clinical trials. We will continue to rely on GC Cell at least partially for manufacturing our product candidates in the near term, particularly for supply in the EU. Any disruption in the supply of our product candidates could result in delays in our clinical trials, which would materially adversely affect our business, financial condition, results of operations and growth prospects.

Our partial reliance on third parties for manufacturing increases the risk that supply of our product candidates may become limited or interrupted or may not be of satisfactory quality and quantity.

While we have built our own clinical manufacturing facility, we currently do not own or operate our own commercial-scale manufacturing facilities and outsource the manufacturing of our product candidates to third parties, including GC Cell. Moreover, while we are operating our own clinical manufacturing facility and may decide to build our own commercial-scale manufacturing facility, we currently have limited personnel with experience in drug manufacturing and currently lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale. Our reliance on GC Cell and on a limited number of third-party manufacturers exposes us to the following risks:

We may continue to depend on certain third-party manufacturers and we may be unable to identify alternative manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA or comparable foreign regulatory authorities may require us to submit additional information or have questions regarding any replacement contractor. This may require new testing and regulatory interactions. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, the production of our products.

- GC Cell or any future third-party manufacturer might be unable to timely formulate and manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any.
- GC Cell and any other contract manufacturers may not be able to execute our manufacturing procedures appropriately.
- GC Cell and any future contract manufacturers may not perform as agreed 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.
- Manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Administration, corresponding state agencies and comparable foreign regulatory authorities to monitor and ensure strict compliance with cGMP and other government regulations and corresponding foreign requirements. We have limited control over third-party manufacturers' compliance with these regulations and standards. Despite our efforts to audit and verify regulatory compliance, one or more of our third-party manufacturing vendors may be found on regulatory inspection by the FDA or other comparable foreign regulatory authorities to be noncompliant with cGMP regulations.
- 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 process for our products.
- GC Cell and any future third-party manufacturers could breach their agreement with us.

Though we have built our own clinical manufacturing facility, we expect that we will continue to rely on third parties for various manufacturing needs.

Manufacturers of pharmaceutical products must comply with strictly enforced cGMP requirements, state and federal regulations, as well as foreign requirements when applicable. Any failure of us or our contract manufacturing organizations to adhere to or document compliance to such regulatory requirements could lead to a delay or interruption in the availability of our program materials for clinical study or enforcement action from the FDA or comparable foreign regulatory authorities. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulatory requirements could result in sanctions being imposed on us, including shutdown of the third-party vendor or invalidation of drug product lots or processes, clinical holds, fines, injunctions, civil penalties, delays, suspension, variation or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates, if approved, and significantly harm our business, financial condition, results of operations and prospects. Our potential future dependence upon others for the manufacture of our product candidates may also adversely affect our future profit margins and our ability to commercialize any product candidates that receive regulatory approval on a timely and competitive basis.

We are dependent on third parties to acquire, ship and store our cord blood units, NK cell master cell banks and drug product lots, viral vectors, and master and working feeder cell banks, and any disruption, quality concerns, damage or loss would cause delays in replacement and our business could suffer.

Our product candidates and certain other materials generated or used during their production, including cord blood units, viral vectors and working feeder cell banks, are acquired from and shipped by third parties and stored in freezers maintained by us and by third parties. In addition, our master cell banks are stored in freezers maintained by third parties. If there is a disruption to the supply of these materials, if available materials fail to meet quality standards, or if any of these materials are damaged while in transit or while stored at these facilities, including by the loss or malfunction of these freezers or back-up power systems, as well as by damage from fire, power loss or other natural disasters, we would need to establish replacement products, which could adversely impact our clinical supply and delay our clinical trials and preclinical studies. If we are unable to establish replacement materials in a timely fashion, we could incur significant additional expenses and potential liability to our clinical trial patients whose treatment is delayed, and our business could suffer.

Our cell therapy products depend on the availability of reagents and specialized materials and equipment, including cord blood and viral vectors, which in each case are required to be acceptable to the FDA and comparable foreign regulatory authorities, and such reagents, materials, and equipment may not be available to us on acceptable terms or at all. We and our third-party manufacturers rely on third-party suppliers for various components, materials and equipment required for the manufacture of our product candidates, some of which are single-source products, and do not have supply arrangements for certain of these components.

Manufacturing of our product candidates, including by GC Cell and certain other of our third-party manufacturers, requires many reagents and other specialty materials and equipment, including cord blood and viral vectors, some of which are sourced from sole suppliers. Reagents and other key materials from these suppliers may have inconsistent attributes and introduce variability into our manufactured product candidates, which may contribute to possible adverse events. We and our third-party manufacturers rely on the general commercial availability of materials required for the manufacture of our product candidates, and do not have supply contracts with many of these suppliers and may not be able to obtain supply contracts with them on acceptable terms or at all. Even if we or our third-party manufacturers are able to enter into such contracts, we may be limited to a sole third-party for the supply of certain required components. An inability by us or our third-party manufacturers to continue to source product from any of these suppliers, which could be due to regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, availability of raw materials, unexpected demands, or quality issues, could adversely affect our ability to satisfy demand for our product candidates, which could adversely and materially affect our product sales and operating results or our ability to conduct clinical trials, either of which could significantly harm our business.

If we or our third-party manufacturers are required to change suppliers, or modify the components, equipment, materials or disposables used for the manufacture of our product candidates, we may be required to change our manufacturing operations or clinical trial protocols or to provide additional data to regulatory authorities in order to use any alternative components, equipment, materials or disposables, any of which could set back, delay, or increase the costs required to complete our clinical development and commercialization of our product candidates. Additionally, any such change or modification may adversely affect the safety, efficacy, stability, or potency of our product candidates, and could adversely affect our clinical development of our product candidates and harm our business.

If our third-party suppliers use hazardous, non-hazardous, biological or other 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. We and our suppliers are subject to federal, state and local laws and regulations in the United States and by foreign governmental authorities governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that we and our suppliers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, neither we nor our suppliers can 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 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.

Any contamination or interruption in our manufacturing process, shortages of raw materials or failure of our suppliers to deliver necessary components could result in delays in our clinical development or marketing schedules.

Given the nature of cell therapy manufacturing, there is a risk of contamination. If microbial, viral or other contaminants are discovered in our product candidates or in any of the manufacturing facilities in which products or other materials are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Any contamination could adversely affect our ability to produce product candidates on schedule and could, therefore, delay our clinical trials, harm our results of operations and cause reputational damage. Some of the raw materials required in our manufacturing process are derived from biologic sources. These raw materials are difficult to procure and may be subject to contamination or recall. A material shortage, contamination, recall or restriction on the use of biologically derived substances in the manufacture of our product candidates could adversely impact or disrupt the commercial manufacturing or the production of clinical material, which could adversely affect our development timelines and our business, financial condition, results of operations and prospects.

Risks Related to Commercialization of 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.

The biopharmaceutical industry in general, and the cell therapy field in particular, is characterized by rapidly advancing and changing technologies, intense competition and a strong emphasis on intellectual property. We face substantial and increasing competition from large and specialty biopharmaceutical companies, as well as public and private medical research institutions and governmental agencies. A large number of cell therapy companies with capabilities and expertise in oncology are advancing development programs in autoimmune diseases. Our known biopharmaceutical competitors developing allogeneic CAR-NK cell or CAR-T cell therapies currently include, among others, Adicet Bio, Inc., Autolus Therapeutics plc, Cabaletta Bio, Inc., Caribou Biosciences, Inc., Cartesian Therapeutics, Inc., Century Therapeutics, Inc., Fate Therapeutics, Inc., Galapagos NV, Gracell Biopharmaceuticals, Inc. (acquired by AstraZeneca), ImmPACT Bio USA, Inc. (acquired by Lyell Immunopharma), Juno Therapeutics, Inc. (acquired by BMS), Kite Pharma (acquired by Gilead), Kyverna Therapeutics, Inc., Nkarta, Inc., Novartis AG, Sana Biotechnology, Inc., Shoreline Biosciences Inc., Takeda Pharmaceuticals Company Limited and Wugen, Inc.

Our competitors will also include companies that are or will be developing other targeted therapies, including small molecule or antibodies for the same indications that we are targeting. It is also possible that new competitors, including those developing similar products or alternatives to cellular immunotherapy product candidates, may emerge and acquire significant market share. Many of our current or potential competitors have significantly greater financial, technical and human resources, as well as more expertise in research and development, manufacturing, preclinical testing, conducting clinical studies and trials and commercializing and marketing approved products. Mergers and acquisitions in the biopharmaceutical industry may result in even greater resource concentration among a smaller number of competitors.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our product candidates less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, discovering, developing, receiving regulatory and marketing approval for or commercializing drugs before we do, which would have an adverse impact on our business and results of operations. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

We currently have no marketing and sales organization and have no experience as a company in commercializing products, and we may have to invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our products, we may not be able to generate product revenue.

We have no internal sales, marketing or distribution capabilities, nor have we commercialized a product. If any of our product candidates ultimately receives regulatory approval, we must build a marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize each such product in major markets, which will be expensive and time consuming, or collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. We have no prior experience as a company in the marketing, sale and distribution of biopharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, our product revenues and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we are not successful in commercializing our products, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our product candidates, if approved, profitably.

Successful sales of our product candidates, if approved, depend on the availability of coverage and adequate reimbursement from third-party payors including governmental healthcare programs, such as Medicare and Medicaid, managed care organizations and commercial payors, among others. Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In addition, because our product candidates represent new approaches to the treatment of autoimmune disease and cancer, we cannot accurately estimate the potential revenue from our product candidates. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may also be particularly difficult because of the higher prices often associated with such drugs. Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Obtaining coverage and adequate reimbursement from third-party payors is critical to new product acceptance.

Third-party payors 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;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement 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, if the resulting reimbursement rates are insufficient, hospitals may not approve our product for use in their facility or third-party payors may require co-payments that patients find unacceptably high. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates. Separate reimbursement for the product itself may or may not be available. Instead, the hospital or administering physician may be reimbursed only for providing the treatment or procedure in which our product is used. Further, from time to time, the Centers for Medicare & Medicaid Services (CMS) revises the reimbursement systems used to reimburse healthcare providers, including the Medicare Physician Fee Schedule and Outpatient Prospective Payment System, which may result in reduced Medicare payments. In some cases, private third-party payors rely on all or portions of Medicare payment systems to determine payment rates. Changes to government healthcare programs that reduce payments under these programs may negatively impact payments from private third-party payors, and reduce the willingness of physicians to use 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. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Additionally, any companion diagnostic test that we develop will be required to obtain coverage and reimbursement separate and apart from the coverage and reimbursement we seek for our product candidates, if approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

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. Outside the United States, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. In some foreign countries, particularly those in Europe, 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. The EU provides options for EU Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. An EU Member State may approve a specific price for the medicinal product, it may refuse to reimburse a product at the price set by the manufacturer or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Many EU Member States also periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status. Moreover, in order to obtain reimbursement for our products in some European countries, including some EU Member States, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. This Health Technology Assessment (HTA) of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States. The downward pressure on healthcare costs has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country. Even if a pharmaceutical product obtains a marketing authorization in the EU, there can be no assurance that reimbursement for such product will be secured on a timely basis or at all.

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if government and other third-party payors fail to provide coverage and adequate reimbursement. We expect downward pressure on pharmaceutical pricing to continue. Further, coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any product candidate that we may develop.

The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare professionals, pharmaceutical companies or others selling or otherwise coming into contact with our products. On occasion, large judgments have been awarded in class action lawsuits based on products that had unanticipated adverse effects. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation and significant negative media attention;
- withdrawal of participants from our clinical trials;
- significant costs to defend the related litigation and related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- inability to commercialize our product candidates;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- decreased demand for our product candidates, if approved for commercial sale; and
- loss of revenue.

Risks Related to Government Regulation

The regulatory approval process of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable, and even if we complete the necessary clinical trials, we cannot predict when, or if, we will obtain regulatory approval for any of our product candidates, and any such regulatory approval may be for a more narrow indication than we seek.

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing, and distribution of drug products, including biologics, are subject to extensive regulation by the FDA and comparable foreign regulatory authorities in and outside the United States. We are not permitted to market any biological drug product in the United States or outside the United States until we receive approval of a BLA from the FDA or similar approvals from comparable foreign regulatory authorities. We have not previously submitted a BLA to the FDA, or similar approval filings to comparable foreign authorities. A BLA and similar applications must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety and effectiveness for each desired indication. The BLA and similar applications must also include significant information regarding the chemistry, manufacturing and controls for the product, including with respect to chain of identity and chain of custody of the product.

Our product candidates could fail to receive regulatory approval from the FDA or a comparable foreign regulatory authority for many reasons, including:

•disagreement with the design or conduct of our clinical trials;

•failure to demonstrate to the satisfaction of regulatory authorities that our product candidates are safe and effective, or have a positive benefit/risk profile for its proposed indication;

•failure of clinical trials to meet the level of statistical significance required for approval;

•disagreement with our interpretation of data from preclinical studies or clinical trials;

•the insufficiency of data collected from clinical trials of our product candidates to support the submission and filing of a BLA or other submission or to obtain regulatory approval;

•failure to obtain approval of our manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies or our own manufacturing facility; or

•changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects. The FDA or a comparable foreign regulatory authority may require more information, including additional preclinical or clinical data to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. If we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request (including failing to approve the most commercially promising indications), may grant approval contingent on the performance of costly post-marketing clinical studies, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Even if our product candidates meet their safety and efficacy endpoints in clinical trials, the regulatory authorities may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval.

We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support licensure. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain licensure of the product candidates based on the completed clinical trials, as the FDA often adheres to the Advisory Committee's recommendations. Similar requirements may apply outside the United States.

Similar requirements apply in the EU. The EMA has a Committee for Advanced Therapies (CAT), that is responsible for assessing the quality, safety and efficacy of advanced therapy medicinal products (ATMPs). ATMPs include gene therapy medicinal products, somatic-cell therapy medicinal products and tissue-engineered medicines. The role of the CAT is to prepare a draft opinion on an application for marketing authorization for ATMP candidates that is submitted to the EMA for subsequent review by the Committee for Medicinal Products for Human Use (CHMP). In the EU, the development and evaluation of an ATMP must be considered in the context of the relevant EU guidelines. The EMA may issue new guidelines concerning the development and marketing authorization for gene therapy medicinal products and require that we comply with these new guidelines. Similarly complex regulatory environments exist in other jurisdictions in which we might consider seeking regulatory approvals for our product candidates, further complicating the regulatory landscape.

In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical trials and the review process. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and approval may not be obtained. For instance, the regulatory landscape related to clinical trials in the EU recently evolved. The EU Clinical Trials Regulation, (CTR), which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each EU Member State, leading to a single decision for each EU Member State. The assessment procedure for the authorization of clinical trials has been harmonized as well, including a joint assessment by all EU Member States concerned, and a separate assessment by each EU Member State with respect to specific requirements related to its own territory, including ethics rules. Each EU Member State's decision is communicated to the sponsor via the centralized EU portal. Once the clinical trial approved, clinical study development may proceed. The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. For clinical trials in relation to which application for approval was made on the basis of the Clinical Trials Directive before (i) January 31, 2022, or (ii) between January 31, 2022 and January 31, 2023 and for which the sponsor has opted for the application of the Clinical Trials Directive, the Clinical Trials Directive will continue to apply on a transitional basis until January 31, 2025. By that date, all ongoing trials will become subject to the provisions of the CTR. The CTR will apply to clinical trials from an earlier date if the related clinical trial application was made on the basis of the CTR or if the clinical trial has already transitioned to the CTR framework before January 31, 2025. Compliance with the CTR requirements by us and our third-party service providers, such as CROs, may impact our developments plans.

In addition, the EU pharmaceutical legislation is currently the subject of proposals for a complete review, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. On April 26, 2023, the European Commission adopted a proposal for a new Directive and Regulation to revise the existing pharmaceutical legislation. If adopted in the form proposed, the recent European Commission proposals to revise the existing EU laws governing authorization of medicinal products may result in a decrease in data and market exclusivity opportunities for our product candidates in the EU and make them open to generic or biosimilar competition earlier than is currently the case with a related reduction in reimbursement status. The proposed revisions remain to be agreed and adopted by the European Parliament and European Council and the proposals may therefore be substantially revised before adoption, the date of which cannot currently be anticipated. The revisions may however have a significant impact on the pharmaceutical industry and our business in the long term.

Regulatory authorities also may approve a product candidate for more limited indications than requested or they may impose significant limitations in the form of narrow indications, warnings or a risk evaluation and mitigation strategy (REMS) or comparable foreign strategies. These regulatory authorities may require labeling that includes precautions or contra-indications with respect to conditions of use, or they may grant approval subject to the performance of costly post-marketing clinical trials. In addition, regulatory authorities may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates and materially adversely affect our business, financial condition, results of operations and prospects.

The regulatory landscape that will govern our product candidates is uncertain; regulations relating to cell therapy products are still developing, and changes in regulatory requirements could result in delays or discontinuation of development of our product candidates or unexpected costs in obtaining regulatory approval.

Because we are developing novel NK cell therapy product candidates that are unique biological entities, the regulatory requirements that we will be subject to are not entirely clear and may change. Regulatory requirements in the United States and in other countries governing cell therapy products have changed frequently and the FDA or comparable foreign regulatory authorities may change the requirements, or identify different regulatory pathways, for approval for any of our product candidates. For example, within the FDA, the CBER restructured and created a new Office of Tissues and Advanced Therapies to better align its oversight activities with FDA Centers for Drugs and Medical Devices. It is possible that over time new or different divisions may be established or be granted the responsibility for regulating cell therapy products, including NK and CAR-NK cell products such as ours. As a result, we may be required to change our regulatory strategy or to modify our applications for regulatory approval, which could delay and impair our ability to complete the preclinical and clinical development and manufacture of, and obtain regulatory approval for, our product candidates.

In addition to FDA oversight and oversight by IRBs under guidelines promulgated by the National Institutes of Health (NIH) gene therapy clinical trials are also subject to review and oversight by an institutional biosafety committee (IBC) a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. Before a clinical study can begin at any institution, that institution's IRB, and its IBC assesses the safety of the research and identifies any potential risk to public health or the environment. While the NIH guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH guidelines voluntarily follow them. Moreover, serious adverse events or developments in clinical trials of cell therapy product candidates conducted by others may cause the FDA or comparable foreign regulatory authorities to initiate a clinical hold on our clinical trials or otherwise change the requirements for approval of any of our product candidates. Although the FDA decides whether individual gene therapy protocols may proceed, the review process and determinations of other reviewing bodies can impede or delay the initiation of a clinical trial, even if the FDA has reviewed the trial and approved its initiation. Changes in regulatory authorities and advisory groups, or any new requirements or guidelines they promulgate, may lengthen the regulatory review process, require us to perform additional studies, increase our development and manufacturing costs, lead to changes in regulatory pathways, positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. In addition, adverse developments in clinical trials of cell therapy products conducted by others may cause the FDA or comparable foreign regulatory authorities to change the requirements for approval of any of our product candidates.

These various regulatory review committees and advisory groups and new or revised guidelines that they promulgate from time to time may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. Even if our product candidates obtain required regulatory approvals, such approvals may later be withdrawn as a result of changes in regulations or the interpretation of regulations by applicable regulatory authorities.

Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to operate our business as planned and to generate sufficient product revenue to maintain our business.

The FDA, the EMA and other comparable foreign regulatory authorities may not accept data from trials conducted in locations outside of their jurisdiction.

We may choose to conduct international clinical trials in the future. The acceptance of study data by the FDA, the EMA or other comparable foreign regulatory authority from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the United States population and United States medical practice; (ii) the trials are performed by clinical investigators of recognized competence and pursuant to current GCP requirements; and (iii) the FDA is able to validate the data through an on-site inspection or other appropriate mean. Additionally, the FDA's clinical trial requirements, including the adequacy of the patient population studied and statistical powering, must be met. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA, the EMA or any applicable foreign regulatory authority will accept data from trials conducted outside of its applicable jurisdiction. If the FDA, the EMA or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval for commercialization in the applicable jurisdiction.

We may seek orphan drug designation for some or all of our product candidates across various indications, but we may be unable to obtain such designations or to maintain the benefits associated with orphan drug designation, including market exclusivity, which may cause our revenue, if any, to be reduced.

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. In order to obtain orphan drug designation, the request must be made before submitting a BLA. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. In the EU a medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention or treatment of a life threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition. The application for orphan designation must be submitted before the application for marketing authorization.

If a product that has orphan drug designation subsequently receives the first FDA approval of that particular product 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 drug (including biologic) for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan drug exclusivity or if FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. As a result, even if one of our product candidates receives orphan exclusivity, the FDA can still approve other biologics that do not have the same principal molecular structural features for use in treating the same indication or disease or the same biologic for a different indication or disease during the exclusivity period. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product or if a subsequent applicant demonstrates clinical superiority over our product.

In the EU, orphan designation entitles a party to financial incentives such as reduction of fees, fee waivers, protocol assistance and access to the centralized marketing authorization procedure. Moreover, upon grant of a marketing authorization and assuming the requirement for orphan designation are also met at the time the marketing authorization is granted, orphan medicinal products are entitled to a ten-year period of market exclusivity for the approved therapeutic indication. The period of exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed Pediatric Investigation Plan. However, during such period, marketing authorizations may be granted to a similar medicinal product with the same orphan indication if: (i) the applicant can establish that the second medicinal product, although similar to the orphan medicinal product already authorized is safer, more effective or otherwise clinically superior to the orphan medicinal product already authorized; (ii) the marketing authorization holder for the orphan medicinal product grants its consent; or (iii) if the marketing authorization holder of the orphan medicinal product is unable to supply sufficient quantities of product. The EU exclusivity period can be reduced to six years, if, at the end of the fifth year a medicinal product no longer meets the criteria for orphan designation (i.e. the prevalence of the condition has increased above the orphan designation threshold or it is judged that the product is sufficiently profitable so as not to justify maintenance of market exclusivity).

We have received orphan drug designation for AB-201 in the United States, for the treatment of gastric and gastroesophageal junction cancer. Additionally, we may seek orphan drug designation for some or all of our product candidates in specific orphan indications in which there is a medically plausible basis for the use of these products. Even if we obtain orphan drug designation, exclusive marketing rights in the United States may be limited if we 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 we are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition, or if a subsequent applicant demonstrates clinical superiority over our products, if approved. Similar considerations may apply outside the United States. In addition, although we may seek orphan drug designation for other product candidates, we may never receive such designations In addition, orphan drug exclusivity does not prevent the FDA or European Commission from approving competing drugs for the same or similar indication containing a different active ingredient. In addition, if a subsequent drug is approved for marketing for the same or a similar indication as any of our product candidates that receive marketing approval, we may face increased competition and lose market share regardless of orphan drug exclusivity. 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.

We may seek special designations by the regulatory authorities to expedite regulatory approvals, but may not be successful in receiving these designations, and even if received, they may not benefit the development and regulatory approval process.

We may seek various designations by regulatory authorities, such as Regenerative Medicine Advanced Therapy Designation (RMAT) Breakthrough Therapy Designation, Fast Track Designation, or PRIority MEdicine (PRIME) Designation from regulatory authorities, for any product candidate that we develop. A product candidate may receive RMAT designation from the FDA if it is a regenerative medicine therapy that is intended to treat, modify, reverse or cure a serious or life-threatening condition, and preliminary clinical evidence indicates that the product candidate has the potential to address an unmet medical need for such 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 studies, patient registries, or other sources of real world evidence (such as electronic health records); through the collection of larger confirmatory data sets; or via post-approval monitoring of all patients treated with such therapy prior to approval of the therapy.

A Breakthrough Therapy is defined by the FDA 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 currently approved therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the study can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens.

If a drug is intended for the treatment of a serious or life-threatening condition or disease, and nonclinical or clinical data demonstrate the potential to address an unmet medical need, the product may qualify for Fast Track Designation, for which sponsors must apply. The FDA has broad discretion whether or not to grant this designation. If granted, fast track designation makes a drug eligible for more frequent interactions with FDA to discuss the development plan and clinical trial design, as well as rolling review of the application, which means that the company can submit completed sections of its marketing application for review prior to completion of the entire submission. Products with Fast Track designation may also be eligible for accelerated approval and priority review, if the relevant criteria are met.

Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the PRIME scheme, which provides incentives similar to the breakthrough therapy designation in the U.S. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicinal products that target unmet medical needs. Eligible products must target conditions for which there is an unmet medical need (there is no satisfactory method of diagnosis, prevention or treatment in the EU or, if there is, the new medicinal product will bring a major therapeutic advantage) and they must demonstrate the potential to address the unmet medical need by introducing new methods of therapy or improving existing ones. Benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted.

Seeking and obtaining these designations is dependent upon results of our clinical program, and we cannot guarantee whether and when we may have the data from our clinical programs to support an application to obtain any such designation. The FDA and the EMA, as applicable, have broad discretion whether or not to grant any of these designations, so even if we believe a particular product candidate is eligible for one or more of these designations, the applicable regulatory authority may determine not to grant it. We received Fast Track designation for AlloNK in combination with either rituximab or obinutuzumab to improve disease activity in patients with class III or class IV LN in February 2024. We also received Fast Track designation for AlloNK for IV infusion in combination with rituximab for the treatment of relapsed or refractory B-NHL origin to improve cancer response rates in January 2023. Fast Track designation does not guarantee an accelerated review of AlloNK or increase the likelihood that AlloNK will receive regulatory approval by the FDA. Even if we do receive the designations we may apply for, we may not experience a faster development process, review or approval compared to conventional FDA or EMA procedures, as applicable. The FDA or EU, as applicable, may rescind any granted designations 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.

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.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while 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 foreign 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 studies 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.

We may also submit marketing applications in other countries. 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. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, 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 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 a REMS in order to approve our product candidates, which could entail 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 a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, the availability of our product candidates to be administered in rheumatology community centers, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping 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. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any BLA, other marketing application and previous responses to inspectional observations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. In addition, the FDA or comparable foreign regulatory authorities could require us to conduct another study to obtain additional safety or biomarker information.

Further, we will be required to comply with FDA and comparable foreign regulatory authorities' promotion and advertising rules, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved uses (known as "off-label use"), limitations on industry-sponsored scientific and educational activities and requirements for promotional activities involving the internet and social media. Although the FDA and comparable foreign regulatory authorities do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, they do restrict promotional communications from companies or their sales force with respect to off-label uses of products for which marketing clearance has not been issued. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party suppliers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS or similar foreign program. Other potential consequences include, 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, untitled letters, warning letters or holds on clinical trials;
- refusal by the FDA or comparable foreign regulatory authority to approve pending applications or supplements to approved applications submitted by us or suspension or revocation of license approvals;

•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.

FDA and comparable foreign 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 or executive action, either in the United States or abroad. For example, certain policies of the any administration may impact our business and industry. 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.

Our relationships with customers, physicians, other healthcare professionals and third-party payors are subject, directly or indirectly, to federal, state, local and foreign healthcare fraud and abuse laws, false claims laws, transparency laws, health information privacy and security laws and other healthcare laws and regulations. If we or our employees, independent contractors, consultants, commercial partners and vendors violate these laws, we could face substantial penalties.

Healthcare professionals and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, third-party payors, customers and others may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may impact, among other things, our clinical research program, as well as our proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services is subject to extensive laws and regulations 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, sales commission, customer incentive and other business arrangements. We may also be subject to federal, state and foreign laws governing the privacy and security of identifiable patient information. The U.S. healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

•the federal Anti-Kickback Statute, which prohibits, among other things, any person or entity from knowingly and willfully, offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, the purchasing, leasing, ordering or arranging for the purchase, lease, or order of any item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. Practices that may be alleged to be intended to induce prescribing, purchases or recommendations, including any payments of more than fair market value, may be subject to scrutiny if they do not qualify for an exception or safe harbor. In addition, a person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation;

•federal civil and criminal false claims laws, including the federal civil False Claims Act (FCA) and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other federal government programs that are false or fraudulent or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government, including federal healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. Private individuals, commonly known as "whistleblowers," can bring federal civil FCA qui tam actions, on behalf of the government and such individuals and may share in amounts paid by the entity to the government in recovery or settlement;

•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, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by any trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

•HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), and their respective implementing regulations, which impose requirements on covered entities, including certain healthcare providers, health plans and healthcare clearinghouses, and their respective business associates that perform services for them that involve creating, receiving maintaining or transmitting protected health information (PHI) and their subcontractors that use, disclose, access, or otherwise process PHI, relating to the privacy, security and transmission of individually identifiable health information. Penalties for HIPAA violations can be significant. They vary greatly depending on the nature of violation, and could include civil monetary or criminal penalties. HIPAA also authorizes state attorneys general to file suit under HIPAA on behalf of state residents. Courts can award damages, costs and attorneys' fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to sue us in civil court for HIPAA violations, its standards have been used as the basis for a duty of care claim in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI; the federal Physician Payments Sunshine Act, which requires certain manufacturers of 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 CMS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and anesthesiologist assistants, and certified nurse midwives), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and

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

Additionally, we may be subject to state, local and foreign equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope. For example, in the EU, interactions between pharmaceutical companies and healthcare professionals and healthcare organizations are also governed by strict laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct both at EU level and in the individual EU Member States. The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of pharmaceutical products is prohibited in the EU. Relationships with healthcare professionals and associations are subject to stringent anti-gift statutes and anti-bribery laws, the scope of which differs across the EU. In addition, national "Sunshine Acts" may require pharmaceutical companies to report/publish transfers of value provided to healthcare professionals and associations on a regular (e.g., annual) basis.

Also, we may be subject to the following: state and foreign anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental, third-party payors, including private insurers, or that apply regardless of payor; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state and local laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare professionals or marketing expenditures; state and foreign laws that require the reporting of information related to drug pricing; state and local laws requiring the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities, including certain arrangements we have with physicians who are paid in the form of stock or stock options for services provided to us, could be subject to challenge under one or more of such laws. If we or our employees, independent contractors, consultants, commercial partners and vendors violate these laws, we may be subject to investigations, enforcement actions and/or significant penalties. 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 significant civil, criminal and administrative penalties, damages, disgorgement, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, 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 expect the product candidates we develop will be regulated as biologics, and therefore they may be subject to competition sooner than anticipated.

The Biologics Price Competition and Innovation Act of 2009 (BPCIA) was enacted as part of the Patient Protection Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the Affordable Care Act), to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an approved biologic. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the reference product was approved under a BLA. 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. While it is uncertain when processes intended to implement BPCIA may be fully adopted by the FDA, any of these processes could have a material adverse effect on the future commercial prospects for our biological products.

We believe that any of the product candidates we develop that is approved in the United States as a biological product under a BLA, if any, 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 the subject product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

In the European Union, there is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product. For such products, the results of appropriate preclinical or clinical trials must be provided in support of an application for MA. Guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product.

In addition, the approval of a biologic product biosimilar to one of our products could have a material adverse impact on our business as it may be significantly less costly to bring to market and may be priced significantly lower than our products.

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

The use of allogeneic NK cells as a potential autoimmune disease or cancer treatment may not become broadly accepted by physicians, patients, hospitals, rheumatology clinics, cancer treatment centers and others in the medical community. Factors that will influence whether our product candidates are accepted in the market include:

- the clinical indications for which our product candidates are approved;
- physicians, hospitals, rheumatology clinics, cancer treatment centers and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the incidence and severity of any side effects;
- product labeling or product insert requirements of the FDA or comparable foreign regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA or comparable foreign regulatory authorities;
- the availability of our product candidates to be administered in rheumatology community centers;
- the timing of market introduction of our product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- our pricing and the availability of coverage and adequate reimbursement by third-party payors, including government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage and adequate reimbursement by third-party payors, including 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, rheumatology clinics, 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.

The advancement of healthcare reform may negatively impact our ability to profitably sell our product candidates, if approved.

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could impact our ability to profitably sell our product candidates, if approved. In particular, in 2010 the Affordable Care Act was enacted. The Affordable Care Act and its implementing regulations, among other things, revised the methodology by which rebates owed by manufacturers to the state and federal government for covered outpatient drugs and certain biologics, including our product candidates, under the Medicaid drug rebate program are calculated, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid drug rebate program, extended the Medicaid drug rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, and provided incentives to programs that increase the federal government's comparative effectiveness research. Additionally, the Affordable Care Act allowed states to implement expanded eligibility criteria for Medicaid programs, imposed a new Medicare Part D coverage gap discount program, expanded the entities eligible for discounts under the Public Health Service pharmaceutical pricing program and implemented a new Patient-Centered Outcomes Research Institute.

Since its enactment, there have been executive, judicial and political challenges to certain aspects of the Affordable Care Act. For example, on June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the Affordable Care Act will remain in effect in its current form. It is unclear how other healthcare reform measures of the Biden administration, if any, will impact our business.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted, including aggregate reductions to Medicare payments to providers, which went into effect beginning on April 1, 2013 and due to subsequent legislative amendments to the statute will stay in effect through 2032, unless additional Congressional action is taken. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminated the statutory Medicaid drug rebate cap, which was previously set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning on January 1, 2024. In addition, Congress is considering health reform measures as part of other health reform initiatives. 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. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates. In addition, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient assistance programs, and reform government program reimbursement methodologies for drugs. In July 2021, the Biden Administration released an executive order, "Promoting Competition in the American Economy," which contained provisions relating to prescription drugs. On September 9, 2021, in response to this executive order, the U.S. Department of Health and Human Services (HHS) released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the Inflation Reduction Act of 2022 (IRA), among other things, (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" for such drugs and biologics under the law, and (ii) imposes rebates with respect to certain drugs and biologics covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions took effect progressively starting in fiscal year 2023. On August 15, 2024, HHS announced the agreed-upon reimbursement prices of the first ten drugs that were subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. HHS will select up to fifteen additional drugs covered under Part D for price negotiation in 2025. In response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures and, in some cases, designed to encourage importation from other countries and bulk purchasing.

In the EU, similar developments may affect our ability to profitably commercialize our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or Member State level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicinal products, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU Member States have resulted in restrictions on the pricing and reimbursement of medicinal products by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize our product candidates, if approved. In markets outside of the United States and EU, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

On December 13, 2021, Regulation No 2021/2282 on HTA amending Directive 2011/24/EU, was adopted in the EU. This Regulation, which entered into force in January 2022 and will apply as of January 2025, is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. The Regulation foresees a three-year transitional period and will permit EU Member States to use common HTA tools, methodologies and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. If we are unable to maintain favorable pricing and reimbursement status in EU Member States for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected.

We cannot predict the initiatives that may be adopted in the future, particularly in light of the upcoming U.S. Presidential and Congressional elections. 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 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.

We are subject to stringent and changing obligations related to data privacy and information security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions, litigation, fines and penalties, a disruption of our business operations, reputational harm and other adverse impacts to our business and financial condition.

We process sensitive and confidential information, including certain personal information of our employees and contractors, which subjects us to various obligations related to data privacy and information security. The global data protection landscape is rapidly evolving, and we and the third parties upon which we rely (including our collaborators and third-party providers) may be or become subject to federal, state and foreign data privacy and information security laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements and other obligations relating to data privacy and security, including in connection with clinical trials in the United States and abroad. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. Such laws may also be inconsistent with or restrict our collection, storage, transfer, use and disclosure of personal information and may require changes to our data processing practices and policies, including the acceptance of more onerous obligations in our contracts or additional costs, and we may be unable to make such changes and modifications in a commercially reasonable manner, or at all.

In the United States, numerous federal and state laws and regulations, including HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or collectively, HIPAA, federal health information privacy laws, state data breach notification laws, state health information privacy laws and federal, state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws govern the processing of health-related and other personal information could apply to our operations or the operations of the third parties upon which we rely. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) which may be subject to privacy and security requirements under HIPAA. Depending on the facts and circumstances, we could be subject to significant penalties if we violate HIPAA.

In many jurisdictions, enforcement actions and consequences for noncompliance with data privacy and information security laws and regulations are rising. In the United States, these include enforcement actions in response to rules and regulations promulgated under the authority of federal agencies and state attorneys general and legislatures and consumer protection agencies. Many state legislatures have adopted legislation that regulates how businesses operate, including measures relating to data privacy and security and data breaches. For example, California enacted the California Consumer Privacy Act , as amended by the California Privacy Rights Act (collectively, the CCPA), which requires covered businesses that process the personal information of California residents to, among other things: (i) provide certain disclosures to California residents regarding the business's collection, use and disclosure of their personal information; (ii) receive and respond to requests from California residents to access, delete and correct their personal information, or to opt out of certain disclosures of their personal information; and (iii) enter into specific contractual provisions with service providers that process California resident personal information on the business's behalf. Other states have also enacted comprehensive privacy laws that impose certain obligations on covered businesses. Although there are minimum revenue thresholds for companies to be subject to some of these laws and limited exemptions for clinical trial data under the CCPA and similar state comprehensive privacy laws, such laws may impact (possibly significantly) our business activities depending on how they are interpreted, should we become subject to such laws in the future. Similar laws have passed and are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. These developments may further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely.

Foreign data protection laws, including the EU General Data Protection Regulation (EU GDPR) and the United Kingdom General Data Protection Regulation and Data Protection Act 2018 (UK GDPR) (collectively, the GDPR), may also apply to health-related and other personal data obtained outside of the United States and impose strict requirements for processing such data. For example, the GDPR imposes strict requirements for processing the personal data of individuals within the European Economic Area (EEA) and UK or in the context of our activities within the EEA and UK and provides for potential fines of up to the greater of €20 million under the EU GDPR, 17.5 million pounds sterling under the UK GDPR, or, in each case, 4% of annual global revenue of a noncompliant undertaking, temporary or definitive bans on processing data, or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including, in certain circumstances, the United States, and the efficacy and longevity of current transfer mechanisms between the EEA and UK to the United States remains uncertain. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum and the EU-U.S. Data Privacy Framework (DPF) and the UK extension thereto, these mechanisms are subject to legal challenges. If there is no lawful manner for us to transfer personal data from the EEA or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional data privacy and security laws and regulations that may affect how we conduct business.

In addition, privacy advocates and industry groups have regularly proposed, and may propose in the future, self-regulatory standards that may legally or contractually apply to us. We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. We publish privacy policies and other statements regarding data privacy and security. If these policies or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Obligations related to data privacy and security (and individuals' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources, which may necessitate changes to our services, information technologies, systems and practices and to those of any third parties upon which we rely.

Failure by us or the third parties upon which we rely, including our collaborators and third-party providers, to comply with U.S. and foreign data protection laws and regulations and other obligations could result in adverse consequences, including government enforcement actions (which could include civil or criminal penalties), private litigation, mass arbitration demands and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or the third parties upon which we rely obtain information may contractually limit our ability to use and disclose such 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, could result in adverse publicity and could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our business activities may be subject to the U.S. Foreign Corrupt Practices Act (FCPA) and similar anti-bribery and anti-corruption laws of other countries in which we operate, as well as U.S. and certain foreign export controls, trade sanctions and import laws and regulations. Compliance with these legal requirements could limit our ability to compete in foreign markets and subject us to liability if we violate them.

If we expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. Our business activities may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits companies and their employees and third party intermediaries from offering, promising, giving or authorizing the provision of anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action or otherwise 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 public officials, including officials of non-U.S. governments. Additionally, in many other countries, hospitals owned and operated by the government, and doctors and other hospital employees would be considered foreign officials under the FCPA. Recently the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents or contractors, or those of our affiliates, 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 fines, criminal 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 product in one or more countries and could materially damage our reputation, our brand, our international activities, our ability to attract and retain employees and our business.

In addition, our product and activities 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 product, or our failure to obtain any required import or export authorization for our product, when applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our product may create delays in the introduction of our product in international markets or, in some cases, prevent the export of our product to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments and persons targeted by U.S. sanctions. 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. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or product targeted by such regulations, could result in decreased use of our product by, or in our decreased ability to export our product to existing or potential customers with international operations. Any decreased use of our product or limitation on our ability to export or sell access to our product would likely significantly harm our business, financial condition, results of operations and prospects.

We are subject to various laws relating to foreign investment and the export of certain technologies, and our failure to comply with these laws or adequately monitor the compliance of our suppliers and others we do business with could subject us to substantial fines, penalties and even injunctions, the imposition of which on us could have a material adverse effect on the success of our business.

We are subject to U.S. laws that regulate foreign investments in U.S. businesses and access by foreign persons to technology developed and produced in the United States. These laws include Section 721 of the Defense Production Act of 1950, as amended by the Foreign Investment Risk Review Modernization Act of 2018, and the regulations at 31 C.F.R. Parts 800 and 801, as amended, administered by the Committee on Foreign Investment in the United States; and the Export Control Reform Act of 2018, which is being implemented in part through Commerce Department rulemakings to impose new export control restrictions on "emerging and foundational technologies" yet to be fully identified. Application of these laws, including as they are implemented through regulations being developed, may negatively impact our business in various ways, including by restricting our access to capital and markets; limiting the collaborations we may pursue; regulating the export our products, services and technology from the United States and abroad; increasing our costs and the time necessary to obtain required authorizations and to ensure compliance; and threatening monetary fines and other penalties if we do not.

Risks Related to Our Intellectual Property

We depend substantially on intellectual property rights granted under our agreements with GC Cell. If we lose our existing licenses or are unable to acquire or license additional proprietary rights from third parties, we may not be able to continue developing our product candidates.

We are dependent on patents, know-how and proprietary technology, both our own and licensed from others. We depend substantially on our agreements with GC Cell, including the licenses granted thereunder. These licenses may be terminated upon certain conditions. Any termination of these licenses could result in the loss of significant rights and could harm our ability to commercialize our product candidates. For example, our proprietary manufacturing methods depend on technology licensed to us by GC Cell. In addition, GC Cell in-licenses some of the intellectual property rights that GC Cell has licensed to us, or that we have the ability to access under our agreements with GC Cell. To the extent these licensors fail to meet their obligations under their license agreements with GC Cell, which we are not in control of, we may lose the benefits of our license agreements with these licensors. In the future, we may also enter into additional license agreements that are material to the development of our product candidates.

We may also enter into additional agreements, including license agreements, with other parties in the future that impose diligence, development and commercialization timelines, milestone payments, royalties, insurance and other obligations on us. We are also obligated to achieve certain development milestones with respect to licensed products in our fields of use within specified time periods. If we fail to comply with our obligations to GC Cell or any of our other current or future collaborators, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any product candidate that is covered by these agreements, which could adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in us having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

We may rely on third parties from whom we license proprietary technology to file and prosecute patent applications and maintain patents and otherwise protect the intellectual property we license from them. We may have limited control over these activities or any other intellectual property that may be related to our in-licensed intellectual property. For example, we cannot be certain that such activities by these licensors will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We may have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights, or defend certain of the intellectual property that may be licensed to us. In addition, some of our patent rights are co-owned with GC Cell and others, and may in the future be co-owned with other third parties. We may need the cooperation of GC Cell and any future co-owners of our patent rights in order to enforce such patent rights against third parties, and such cooperation may not be provided to us. It is also possible that our licensors' or co-owners' infringement proceeding or defense activities may be less vigorous than if we conduct them ourselves. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

The licensing and acquisition of third-party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. We may not be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire. Furthermore, we may be unable to in-license any compositions, methods of use, processes, or other third-party intellectual property rights from third parties, which we identify as necessary for our product candidates.

If we are unable to obtain and maintain patent protection for our technology and product candidates or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

We rely, and will continue to rely, upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our proprietary manufacturing methods, proprietary technologies, product candidate development programs and product candidates. Our success depends in large part on our ability to secure and maintain patent protection in the United States and other countries with respect to our current product candidates and any future product candidates we may develop. We seek to protect our proprietary position by filing or collaborating with our licensors and co-owners to file patent applications in the United States and abroad related to our proprietary technologies, development programs and product candidates. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Moreover, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

Composition of matter patents for biological and pharmaceutical product candidates often provide a strong form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. We cannot be certain that the claims in our pending patent applications directed to composition of matter of our product candidates will be considered patentable by the United States Patent and Trademark Office (USPTO) or by patent offices in foreign countries. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Method of manufacturing patents protect only the manufacturing process. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product, but manufactured by a method that is outside the scope of the patented manufacturing method. Moreover, even if a competitor's manufacturing process does infringe or contribute to the infringement of method of manufacturing patents, such infringement is difficult to detect and therefore difficult to prevent or prosecute.

It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Therefore, these patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our proprietary products and technology, including current product candidates, any future product candidates we may develop, and our NK cell therapy technology in the United States or in other foreign countries, in whole or in part. Alternately, our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from using our technology or from developing competing products and technologies. It is possible that not all potentially relevant prior art relating to our patents and patent applications has been found, which can prevent a patent from issuing from a pending patent application or later invalidate or narrow the scope of an issued patent. For example, publications of discoveries in the scientific literature often lag behind the actual discoveries, and 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. Even if patents do successfully issue and even if such patents cover our current product candidates, any future product candidates we may develop and our NK cell therapy technology, third parties may challenge their validity, ownership, enforceability or scope thereof, which may result in such patents being narrowed, invalidated, or held unenforceable or circumvented. Any successful challenge to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any of our product candidates or gene regulation technology. In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our product candidate, if approved, or practicing our own patented technology. Our competitors may be able to circumvent our patents by developing similar or alternative product candidates in a non-infringing manner. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate and our NK cell therapy platform under patent protection could be reduced. If any of our patents expire or are challenged, invalidated, circumvented or otherwise limited by third parties prior to the commercialization of our product candidate, and if we do not own or have exclusive rights to other enforceable patents protecting our product candidate or technologies, competitors and other third parties could market products and use processes that are substantially similar, or superior, to ours and our business would suffer.

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

We are a party to intellectual property license agreements with GC Cell which are important to our business, and we expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, royalties and other obligations on us. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, or, in some cases, under other circumstances, the licensor may have the right to terminate the license, in which event we would not be able to market product candidate(s) covered by the license.

The patent position of biotechnology and pharmaceutical companies is generally highly uncertain, involves complex legal, scientific and factual questions, and is characterized by the existence of large numbers of patents and frequent litigation based on allegations of patent or other intellectual property infringement or violation. The standards that the USPTO and its foreign counterparts use to grant patents are not always applied predictably or uniformly. In addition, the laws of jurisdictions outside the United States may not protect our rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. Since patent applications in the United States and other jurisdictions are confidential for a period of time after filing, we cannot be certain that we were the first to file for patents covering our inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in the issuance of patents, or may result in the issuance of patents which fail to protect our technology or products, in whole or in part, or which fail to effectively prevent others from commercializing competitive technologies and products.

The issuance of a patent is not conclusive as to its inventorship, ownership, scope, validity or enforceability and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or 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. We may become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our owned or licensed patent rights. For example, with respect to our licensed patents and jointly owned patents and patent applications from GC Cell, competitors may claim that they invented the inventions claimed in our issued patents or patent applications prior to the inventors of our licensed patents. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Thus, even if our patent applications issue as patents, they may not issue in a form that will provide us with meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage.

Moreover, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent and the protection it affords, is limited. Without patent protection for our current or future product candidates, we may be open to competition from biosimilar versions of such products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

Our commercial success depends, in part, upon our ability to develop, manufacture, market and sell our product candidates without alleged or actual infringement, misappropriation or other violation of the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Litigation relating to infringement or misappropriation of patent and other intellectual property rights in the pharmaceutical and biotechnology industries is common, including patent infringement lawsuits, interferences, derivation and administrative law proceedings, inter partes review and post-grant review before the USPTO, as well as oppositions and similar processes in foreign jurisdictions. The various markets in which we

plan to operate are subject to frequent and extensive litigation regarding patents and other intellectual property rights. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for or obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell, if approved, our product candidates. In addition, many companies in intellectual property-dependent industries, including the biotechnology and pharmaceutical industries, have employed intellectual property litigation as a means to gain an advantage over their competitors. Numerous U.S., EU and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates, and as the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our product candidates may be subject to claims of infringement of the intellectual property rights of third parties. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us. We may be subject to third-party claims including patent infringement, interference or derivation proceedings, post-grant review and inter partes review before the USPTO or similar adversarial proceedings or litigation in other jurisdictions. Even if such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, and the holders of any such patents may be able to block our ability to commercialize the applicable product candidate unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. There may be third-party patents or patent applications with claims to compositions, formulations, or methods of treatment, prevention use, or manufacture of our product candidates or technologies. 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. If any third-party patents were held by a court of competent jurisdiction to cover aspects of our compositions, formulations, or methods of treatment, prevention or use, the holders of any such patents may be able to prohibit our use of those compositions, formulations, methods of treatment, prevention or use or other technologies, effectively blocking our ability to progress the clinical development of or commercialize the applicable product candidate until such patent expires or is finally determined to be invalid or unenforceable or unless we obtained a license.

We also may be subject to third party claims arising from prior employment agreements and/or consulting agreements entered into by our officers, employees, independent contractors and/or consultants. Claims may include breach of nondisclosure, nonuse, noncompetition and non-solicitation provisions, intellectual property assignment and ownership, and misuse or misappropriation of intellectual property, trade secrets and other confidential information, among others. If a court of competent jurisdiction finds that we breached the provisions of third party consulting agreements, we may be prohibited from using certain intellectual property, trade secrets and confidential information, effectively blocking our ability to seek patent protection for our inventions and halting the progress of our clinical development and commercialization efforts.

In addition, defending such claims would cause us to incur substantial expenses and, if successful, could cause us to pay substantial damages if we are found to be infringing a third party's intellectual property rights. These damages potentially include increased damages and attorneys' fees if we are found to have infringed such rights willfully. Further, if a patent infringement suit is brought against us or our third-party service providers, our development, manufacturing or sales activities relating to the product or product candidate that is the subject of the suit may be delayed or terminated, as parties making claims against us may obtain injunctive or other equitable relief. As a result of patent infringement claims, or in order to avoid potential infringement claims, we may choose to seek, or be required to seek, a license from the third party, which may require payment of substantial royalties or fees, or require us to grant a cross-license under our intellectual property rights. These licenses may not be available on reasonable terms or at all. Even if a license can be obtained on reasonable terms, the rights may be nonexclusive, which would give our competitors access to the same intellectual property rights. If we are unable to enter into a license on acceptable terms, we could be prevented from commercializing one or more of our product candidates, or forced to modify such product candidates, or to cease some aspect of our business operations, which could harm our business significantly. We might also be forced to redesign or modify our product candidates so that we no longer infringe the third-party intellectual property rights, which may result in significant cost or delay to us, or which redesign or modification could be impossible or technically infeasible. Even if we were ultimately to prevail, any of these events could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business. Intellectual property litigation, regardless of its outcome, may cause negative publicity, adversely impact prospective customers, cause product shipment delays, or prohibit us from manufacturing, importing, marketing or otherwise commercializing our products, services and technology. In addition, if the breadth or strength of protection provided the patents and patent applications we own or in-license is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Competitors may infringe our patents or other intellectual property. If we or one of our licensors or co-owners were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the United States and in Europe, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness lack of written description, or non-enablement. Third parties might allege unenforceability of our patents because during prosecution of the patent an individual connected with such prosecution withheld relevant information, or made a misleading statement. Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. The outcome of proceedings involving assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity of patents, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution, but that an adverse third party may identify and submit in support of such assertions of invalidity. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Our patents and other intellectual property rights also will not protect our technology if competitors design around our protected technology without infringing our patents or other intellectual property rights.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors view these announcements in a negative light, the price of our common stock could be adversely affected. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have an adverse effect on our ability to compete in the marketplace.

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, manufacture and market our product candidates.

It is possible that our or our licensors' or co-owners' patent searches or analyses, including but not limited to the identification of relevant patents, analysis of the scope of relevant patent claims or determination of the expiration of relevant patents, are not complete or thorough. It is also possible that we have not identified each and every third-party patent and pending application in the United States, Europe and elsewhere that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. For example, in the United States, applications filed before November 29, 2000, and certain applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States, the EU and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our product candidates could be filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our product candidates. After issuance, the scope of patent claims remains subject to construction as 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 product candidates. We may incorrectly determine that our product candidates 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, the EU or elsewhere 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 product candidates, if approved. If we fail to identify or correctly interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay monetary damages, we may be temporarily or permanently prohibited from commercializing our product candidates. We might, if possible, also be forced to redesign our product candidates in a manner that no longer infringes third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

Our intellectual property licenses with third parties may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations to our licensors.

We currently depend, and will continue to depend, on our license agreements, including our agreements with GC Cell. Further development and commercialization of our current or any future product candidates may require us to enter into additional license or collaboration agreements, including, potentially, additional agreements with GC Cell or any of our other licensors. The agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

If any of our licenses or material relationships or any in-licenses upon which our licenses are based are terminated or breached, we may:

•lose our rights to develop and market our products;

•lose patent protection for our products;

•lose rights to important confidential know-how for manufacturing our products;

•experience significant delays in the development or commercialization of our products;

•incur significant extra costs in order to develop, manufacture and commercialize our products;

•not be able to obtain any other licenses on acceptable terms, if at all; or

•incur liability for damages.

These risks apply to any agreements that we may enter into in the future for our products or for any future product candidates. If we experience any of the foregoing, it could have a material adverse effect on our business, financial condition, results or operations and prospects.

Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biotechnology companies, our success is heavily dependent on our intellectual property, particularly our patents. Obtaining and enforcing patents in the biotechnology and genetic medicine industries involve both technological and legal complexity. Therefore, obtaining and enforcing biotechnology and genetic medicine patents is costly, time-consuming and inherently uncertain. In addition, the Leahy-Smith America Invents Act (AIA) which was passed in September 2011, resulted in significant changes to the U.S. patent system. An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned from a "first-to-invent" to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. A third party that files a patent application in the USPTO after that date but before us could therefore be awarded a patent covering an invention of ours even if we made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application and be diligent in filing patent applications, but circumstances could prevent us from promptly filing patent applications on our inventions.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action.

Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. It is not clear what, if any, impact the AIA will have on the operation of our business. However, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensors' or co-owners' patent applications and the enforcement or defense of our or our

licensors' or co-owners' issued patents. We may become involved in opposition, interference, derivation, inter partes review or other proceedings challenging our or our licensors' or co-owners' patent rights, and the outcome of any proceedings are highly uncertain. An adverse determination in any such proceeding could reduce the scope of, or invalidate, our owned or in-licensed patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

Additionally, 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, and there are other open questions under patent law that courts have yet to decisively address. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways and could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. In addition, the European patent system is relatively stringent in the type of amendments that are allowed during prosecution, but, the complexity and uncertainty of European patent laws has also increased in recent years. Complying with these laws and regulations could limit our ability to obtain new patents in the future that may be important for our business.

Further, on June 1, 2023, the European Patent Package (EU Patent Package) regulations were implemented with the goal of providing a single pan-European Unitary Patent and a new European Unified Patent Court (UPC), for litigation involving European patents. Under the UPC, all European patents, including those issued prior to ratification of the European Patent Package, will by default automatically fall under the jurisdiction of the UPC. The UPC provides our competitors with a new forum to centrally revoke our European patents, and allows for the possibility of a competitor to obtain pan-European injunctions. It will be several years before we will understand the scope of patent rights that will be recognized and the strength of patent remedies provided by the UPC. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. We will have the right to opt our patents out of the UPC over the first seven years of the court's existence, but doing so may preclude us from realizing the benefits, if any, of the new unified court.

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

The USPTO, European and other patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO, European and other patent agencies over the lifetime of the patent. While an inadvertent failure to make payment of such fees or to comply with such provisions can in many cases be cured by additional payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance with such provisions will result in the abandonment or lapse of the patent or patent application, and the partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents within prescribed time limits. If we or our licensors or co-owners fail to maintain the patents and patent applications covering our product candidates or if we or our licensors or co-owners otherwise allow our patents or patent applications to be abandoned or lapse, it can create opportunities for competitors to enter the market, which would hurt our competitive position and could impair our ability to successfully progress clinical development of or commercialize our product candidates in any indication for which they may be approved.

We enjoy only limited geographical protection with respect to certain patents and we may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents covering our product candidates in all countries throughout the world would be prohibitively expensive, and even in countries where we have sought protection for our intellectual property, such protection can be less extensive than those in the United States. The requirements for patentability may differ in certain countries, particularly developing countries, and the breadth of patent claims allowed can be inconsistent. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. In-licensing patents covering our product candidates in all countries throughout the world may similarly be prohibitively expensive, if such opportunities are available at all. And in-licensing or filing, prosecuting and defending patents even in only those jurisdictions in which we develop or commercialize our product candidates may be prohibitively expensive or impractical. Competitors may use our and our licensors' and co-owners' technologies in jurisdictions where we have not obtained patent protection or licensed patents to develop their own products and, further, may export otherwise infringing products to territories where we and our licensors and co-owners have patent protection, but where enforcement is not as strong as that in the United States or the EU. These products may compete with our product candidates, and our or our licensors' or co-owners' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. In addition, we may decide to abandon national and regional patent applications while they

are still pending. The grant proceeding of each national or regional patent is an independent proceeding which may lead to situations in which applications may be rejected by the relevant patent office, while substantively similar applications are granted by others. For example, relative to other countries, China has a heightened requirement for patentability and specifically requires a detailed description of medical uses of a claimed drug. Furthermore, generic drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' or co-owners' patents, requiring us or our licensors or co-owners to engage in complex, lengthy and costly litigation or other proceedings. Generic drug manufacturers may develop, seek approval for and launch generic versions of our products. It is also quite common that depending on the country, the scope of patent protection may vary for the same product candidate or technology.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or regulations in the United States and the EU and many companies have encountered significant difficulties in protecting and defending proprietary rights in such jurisdictions. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets or other forms of intellectual property, particularly those relating to biotechnology products, which could make it difficult for us to prevent competitors in some jurisdictions from marketing competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, are likely to result in substantial costs and divert our efforts and attention from other aspects of our business, and additionally could put at risk our or our licensors' or co-owners' patents of being invalidated or interpreted narrowly, could increase the risk of our or our licensors' or co-owners' patent applications not issuing, or could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, while damages or other remedies may be awarded to the adverse party, which may be commercially significant. If we prevail, damages or other remedies awarded to us, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets. If we or our licensors or co-owners encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition in those jurisdictions.

In some jurisdictions including EU countries, compulsory licensing laws compel patent owners to grant licenses to third parties. In addition, some 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 or co-owners are forced to grant a license to third parties under patents relevant to our business, or if we or our licensors or co-owners are prevented from enforcing patent rights against third parties, our competitive position may be substantially impaired in such jurisdictions.

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

The term of any individual patent depends on applicable law in the country where the patent is granted. In the United States, provided all maintenance fees are timely paid, a patent generally has a term of 20 years from its application filing date or earliest claimed non-provisional filing date. Extensions may be available under certain circumstances, but the life of a patent and, correspondingly, the protection it affords is limited. Even if we or our licensors or co-owners obtain patents covering our product candidates, when the terms of all patents covering a product expire, our business may become subject to competition from competitive medications, including generic medications. Given the amount of time required for the development, testing and regulatory review and approval of new product candidates, patents protecting such candidates may expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

In the United States, a patent that covers an FDA-approved drug or biologic may be eligible for a term extension designed to restore the period of the patent term that is lost during the premarket regulatory review process conducted by the FDA. Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act), which permits a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. In the EU, our product candidates

may be eligible for term extensions based on similar legislation. In either jurisdiction, however, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Even if we are granted such extension, the duration of such extension may be less than our request. If we are unable to obtain a patent term extension, or if the term of any such extension is less than our request, the period during which we can enforce our patent rights for that product will be in effect shortened and our competitors may obtain approval to market competing products sooner. The resulting reduction of years of revenue from applicable products could be substantial.

Our proprietary rights may not adequately protect our technologies and product candidates, and do not necessarily address all potential threats to our competitive advantage.

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

- others may be able to make products that are the same as or similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- others, including inventors or developers of our owned or in-licensed patented technologies who may become involved with competitors, may independently develop similar technologies that function as alternatives or replacements for any of our technologies without infringing our intellectual property rights;
- we or our licensors, co-owners, or our other collaboration partners might not have been the first to conceive and reduce to practice the inventions covered by the patents or patent applications that we own, license or will own or license;
- we or our licensors, co-owners, or our other collaboration partners might not have been the first to file patent applications covering certain of the patents or patent applications that we or they own or have obtained a license, or will own or will have obtained a license;
- we or our licensors or co-owners may fail to meet obligations to the U.S. government with respect to in-licensed patents and patent applications funded by U.S. government grants, leading to the loss of patent rights;
- it is possible that our pending patent applications will not result in issued patents;
- it is possible that there are prior public disclosures that could invalidate our or our licensors' or co-owners' patents;
- issued patents that we own or exclusively license may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- we may not exclusively license our patents and, therefore, may not have a competitive advantage if such patents are licensed to others, including for example, under our license agreements with GC Cell, pursuant to which GC Cell and its upstream licensors retain the exclusive right over certain technologies;
- our competitors might conduct research and development activities in countries where we do not have patent rights, or in countries where research and development safe harbor laws exist, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- ownership, validity or enforceability of our or our licensors' or co-owners' patents or patent applications may be challenged by third parties; and
- the patents of third parties or pending or future applications of third parties, if issued, may have an adverse effect on our business.

Our reliance on third parties may require us to share our trade secrets, which increases the possibility that our trade secrets will be misappropriated or disclosed, and confidentiality agreements with employees and third parties may not adequately prevent disclosure of trade secrets and protect other proprietary information.

We consider trade secrets and confidential know-how to be important to our business. We may rely on trade secrets and confidential know-how to protect our technology, especially where patent protection is believed by us to be of limited value. However, trade secrets and confidential know-how are difficult to protect, and we have limited control over the protection of trade secrets and confidential know-how used by our licensors, co-owners, collaborators and suppliers. Because we rely on third parties to manufacture our product candidates, may continue to do so in the future and expect to collaborate with third parties on the development of our current product candidates and any future product candidates we develop, we may, at times, share trade secrets and confidential know-how with them. We also conduct joint research and development programs that may require us to share trade secrets and confidential

know-how under the terms of our research and development partnerships or similar agreements. Under such circumstances, trade secrets and confidential know-how can be difficult to maintain as confidential.

To protect this type of information against disclosure or appropriation by competitors, our policy is to require our employees, consultants, contractors and advisors to enter into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with us 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. However, current or former employees, consultants, contractors and advisers may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. The need to share trade secrets and other confidential know-how increases the risk that such trade secrets and confidential know-how 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 competitive position is based, in part, on our confidential know-how and trade secrets, a competitor's discovery of our trade secrets and/or confidential know-how or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations. Enforcing a claim that a third party obtained illegally and is using trade secrets and/or confidential know-how is expensive, time consuming and unpredictable, and the enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction. Courts outside the United States are sometimes less willing to protect proprietary information, technology and know-how. Further, we may need to share our trade secrets and confidential know-how with future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors.

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 or confidential know-how, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets and confidential know-how, our competitors may discover them, 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 and/or confidential know-how would impair our competitive position and have an adverse impact on our business.

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

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

We may need to license additional intellectual property from third parties, and any such licenses may not be available or may not be available on commercially reasonable terms.

The growth of our business may depend in part on our ability to acquire or in-license additional proprietary rights. For example, our programs may involve product candidates that may require the use of additional proprietary rights held by third parties. Our product candidates may also require specific formulations to work effectively and efficiently. These formulations may be covered by intellectual property rights held by others. We may develop products containing our compositions and pre-existing pharmaceutical compositions. These pharmaceutical products may be covered by intellectual property rights held by others. We may be required by the FDA, or other comparable foreign regulatory authorities to provide a companion diagnostic test or tests with our product candidates. These diagnostic test or tests may be covered by intellectual property rights held by others. We may be unable to acquire or in-license any relevant third-party intellectual property rights that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license under such intellectual property rights, any such license may be non-exclusive, which may allow our competitors access to the same technologies licensed to us.

We may fail to obtain or enforce assignments of intellectual property rights from our employees and contractors.

While it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing an enforceable agreement with each party who in fact conceives or develops intellectual property that we regard as our own. Furthermore, our assignment agreements may not be self-executing or may be breached, and we may be forced to bring or defend claims to determine the ownership of what we regard as our intellectual property, and we may not be successful in such claims. If we fail in bringing or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could materially adversely affect our business, financial condition, results of operations and growth prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees.

Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of trade secrets and other proprietary information.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect trade secrets, confidential know-how, processes for which patents are difficult to enforce, and any other elements of our product discovery and development processes that involve proprietary information or technology that is not covered by patents. Trade secrets, however, may be difficult to protect. Although we require all of our employees to assign their inventions to us, and require all of our employees and key consultants who have access to our confidential know-how, information, or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential 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.

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

We do and will continue to employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our licensors, competitors or potential competitors. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, consultants, collaborators, independent contractors and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us and to not use the know-how or confidential information of their former employer or other third parties, we may be subject to claims that we or our employees, consultants, collaborators or independent contractors have inadvertently or otherwise used or disclosed know-how or confidential information of their former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents.

Litigation may be necessary to defend against these claims. We may not be successful in defending these claims, and if we do fail in defending any such claims, in addition to paying monetary damages, we may lose valuable personnel or intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property, which could result in customers seeking other sources for the technology, or in ceasing from doing business with us. Any such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to progress our clinical development programs or commercialize our technology or product candidate. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful, litigation could result in substantial cost and reputational loss and be a distraction to our management and other employees. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition.

Risks Related to Our Industry and Business

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

As of September 30, 2024, we had 82 full-time employees. We will need to expand our organization, and we may have difficulty identifying, hiring and integrating new personnel. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities

and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

Our future success depends on our ability to retain our key personnel and to attract, retain and motivate qualified personnel.

Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on our executive officers, as well as the other members of our management, scientific and clinical teams. Although we have formal employment agreements with our executive officers, these agreements do not prevent them from terminating their employment with us at any time and, for certain of our executive officers, entitle them to receive severance payments in connection with their voluntary resignation of employment for good reason, as defined in the employment agreements.

If we lose one or more of our executive officers or key employees, our ability to implement our business strategy successfully could be seriously harmed. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of highly specialized skills and experience required to develop, gain regulatory approval of and commercialize our product candidates successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel on acceptable terms given the competition among numerous biopharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be engaged by entities other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to advance the clinical development of and commercialize product candidates will be limited.

If our information technology systems or those of the third parties upon which we rely or our data is or were compromised or fail, we could experience adverse impacts resulting from such compromise or failure, including, but not limited to, interruptions to our operations such as our clinical trials, claims that we breached our data protection obligations, harm to our reputation, and a loss of customers or sales.

In the ordinary course of our business, we and third parties upon which we rely collect, receive, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, share and store (collectively, process) confidential and sensitive data, including intellectual property, pre-clinical and clinical trial data, proprietary business information and personal information of employees, business partners and service providers (collectively, Confidential Information) necessary to conduct our business in our and the third parties' upon which we rely data centers and networks. The secure processing, maintenance and transmission of this Confidential Information is critical to our operations. Despite our security measures, our information technology and infrastructure, and those of third parties upon which we rely, including our current and future CROs, may be vulnerable to attacks, damage and interruption from hackers or internal bad actors, human error, misconfigurations, "bugs" and other technical vulnerabilities, fraud, malfeasance, computer viruses and malware (e.g., ransomware), cyber attacks, social engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), denial or degradation of service attacks, server malfunction, software or hardware failures, loss of data or other information technology assets, adware, attacks enhanced or facilitated by artificial intelligence, natural disasters, terrorism, war and telecommunication and electrical failures or other disruptions. Such threats are prevalent, continue to rise, are increasingly difficult to detect and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel, sophisticated nation states and nation-state supported actors, including via advanced persistent threat intrusions.

Ransomware attacks, including those from organized criminal threat actors, nation-states and nation-state supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions, delays, or outages in our operations, loss of data (including Confidential Information), loss of income, significant extra expenses to restore data or systems, reputational loss and the diversion of funds. To alleviate the financial, operational and reputational impact of a ransomware attack, it may be preferable to make extortion payments, but we may be unwilling or unable to do so (including, for example, if applicable laws or regulations prohibit such payments).

Additionally, as a result of the COVID-19 pandemic, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who continue to work remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities and utilizing network connections, information technology and devices outside our premises or network, including working at home, while in transit and in public locations. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

We rely on third parties to operate critical business systems to process Confidential Information in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email, clinical trials and other functions. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If these parties experience a security breach or other interruption, we could experience adverse consequences. While we may be entitled to damages if these third parties fail to satisfy their data privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain 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 systems and networks or the systems and networks of third parties that support us and our services.

Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. We take steps to detect, mitigate and remediate vulnerabilities in our information technology systems (such as our hardware and/or software and those of third parties upon which we rely). We may not, however, detect and remediate all such vulnerabilities including on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security breach. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection and to remove or obfuscate forensic evidence.

We and certain of the third parties upon which we rely are from time to time subject to cyber attacks and security incidents. Although, to our knowledge, we have not experienced any material security breach to date, any such breach could compromise our networks and the Confidential Information stored there could be accessed, publicly disclosed, lost or stolen. While we have taken steps to protect the security of the Confidential Information that we handle, there can be no assurance that our and the third parties' upon which we rely cybersecurity risk management program and processes, including policies, controls or procedures and other security measures that we have implemented will be fully implemented, complied with or effective in protecting our systems, networks and Confidential Information against current or future security threats. Our security measures could fail and result in unauthorized, accidental or unlawful access to, or disclosure, modification, misuse, loss or destruction of, our Confidential Information, including personal information. We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security breaches. Certain data privacy and security obligations may require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and Confidential Information.

Applicable data privacy and security obligations may require us to notify relevant stakeholders, including affected individuals, regulators and investors, of security breaches. The costs associated with the investigation, remediation and making such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. Any such unauthorized access, disclosure or other loss of Confidential Information experienced by (or perceived to be experienced by) us or a third party upon which we rely could also result in adverse consequences, such as legal claims or proceedings, liability under laws that protect the privacy of personal information, significant regulatory proceedings or penalties, additional reporting requirements or oversight, restrictions on processing Confidential Information, litigation (including class actions), indemnification obligations, monetary fund diversions, diversion of management attention, financial loss, disruptions to our operations and cause a loss of confidence in us and our ability to conduct clinical trials, which could adversely affect our reputation. For example, the loss of preclinical study or clinical trial data from completed, ongoing or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Additionally, theft of our Confidential Information could require substantial expenditures to remedy. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of Confidential Information, we could incur liability and the further development of our product candidates could be delayed. Further, our insurance coverage may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems.

Our business is subject to risks arising from pandemic and epidemic diseases.

The COVID-19 worldwide pandemic presented substantial public health and economic challenges and affected our employees, patients, physicians and other healthcare providers, communities and business operations, as well as the U.S. and global economies and financial markets. Any future pandemic or epidemic disease outbreaks could disrupt the supply chain and the manufacture or shipment of our product candidates for use in our clinical trials and research and preclinical studies and, delay, limit or prevent our employees and CROs from continuing research and development activities, impede our clinical trial initiation and recruitment and the ability of patients to continue in clinical trials, alter the results of the clinical trial due to disease progression in participants, impede testing, monitoring, data collection and analysis and other related activities, any of which could delay our preclinical studies and clinical trials and increase our development costs, and have a material adverse effect on our business, financial condition and results of operations. Any future pandemic or epidemic disease outbreak could also potentially further affect the business of the FDA or other comparable foreign regulatory authorities, which could result in delays in meetings related to our ongoing or planned clinical trials, as well have an adverse impact on global economic conditions, which could have an adverse effect on our business and financial condition, including impairing our ability to raise capital when needed.

Our business could be affected by litigation, government investigations, and enforcement actions.

We currently operate in a number of jurisdictions in a highly regulated industry, and we could be subject to litigation, government investigation and enforcement actions on a variety of matters in the United States or foreign jurisdictions, including, without limitation, intellectual property, regulatory, product liability, environmental, whistleblower, false claims, data privacy and security, anti-kickback, anti-bribery, securities, commercial, employment and other claims and legal proceedings that may arise from conducting our business. Any determination that our operations or activities are not in compliance with existing laws or regulations could result in the imposition of fines, civil and criminal penalties, equitable remedies, including disgorgement, injunctive relief and/or other sanctions against us, and remediation of any such findings could have an adverse effect on our business operations.

Legal proceedings, government investigations and enforcement actions can be expensive and time-consuming. An adverse outcome resulting from any such proceedings, investigations or enforcement actions could result in significant damages awards, fines, penalties, exclusion from the federal healthcare programs, healthcare debarment, injunctive relief, product recalls, reputational damage and modifications of our business practices, which could have a material adverse effect on our business and results of operations. Even if such a proceeding, investigation, or enforcement action is ultimately decided in our favor, the investigation and defense thereof could require substantial financial and management resources.

Our employees and independent contractors, including consultants, vendors and any third parties we may engage in connection with development and commercialization may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could harm our business.

Misconduct by our employees and independent contractors, including consultants, vendors and any third parties we may engage in connection with development and commercialization, could include intentional, reckless or negligent conduct or unauthorized activities that violate: (1) the laws and regulations of the FDA, EU and comparable foreign regulatory authorities, including those laws that require the reporting of true, complete and accurate information to such authorities; (2) manufacturing standards; (3) data privacy and security laws, and fraud and abuse and other healthcare laws and regulations; or (4) other laws that require the reporting of true, complete and accurate financial information and data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creation of fraudulent data in preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid, other U.S. federal healthcare programs or healthcare programs in other jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations.

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

We have incurred losses during our history, we expect to continue to incur significant losses for the foreseeable future, and we may never achieve profitability. Under current law, U.S. federal net operating losses (NOLs) incurred in taxable years beginning after December 31, 2017, can be carried forward indefinitely, but the deductibility of such U.S. federal NOLs in a taxable year is limited to 80% of taxable income in such year.

As of December 31, 2023, we had federal net operating loss carryforwards of approximately $73.0 million and state net operating loss carryforwards of $91.2 million. All of our federal net operating loss carryforwards as of December 31, 2023 can be carried forward indefinitely. State net operating loss carryforwards begin to expire in 2039. Our NOL carryforwards are subject to review and possible adjustment by the U.S. and state tax authorities.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Code), and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50 percentage point change (by value) in its equity ownership over a rolling three-year period, the corporation's ability to use its pre-change NOL carryforwards, research and development (R&D) credits and certain other tax attributes to offset its post-change income or taxes may be limited. This could limit the amount of NOLs, R&D credit carryforwards or other applicable tax attributes that we can utilize annually to offset future taxable income or tax liabilities. We have not completed a Section 382 ownership change analysis. If ownership changes have occurred or occur in the future, the amount of remaining tax attribute carryforwards available to offset taxable income and income tax expense in future years may be restricted or eliminated. Changes to U.S. tax rules in respect of the utilization of NOLs, R&D credits and other applicable tax attributes could further affect our ability to use our tax attributes in the future. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For example, California recently imposed limits on the usability of California state NOL carryforwards and certain state tax credits in tax years beginning after 2023 and before 2027. As a result, we may be unable to use all or a material portion of our NOL carryforwards and other tax attributes, which could adversely affect our future cash flows.

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

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, legislation informally titled the Tax Cuts and Jobs Act, the Coronavirus Aid, Relief, and Economic Security Act and the Inflation Reduction Act enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation. In addition, it is uncertain if and to what extent various states will conform to such legislation or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings and the deductibility of expenses or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges and could increase our future U.S. tax expense.

Investors' expectations of our performance relating to environmental, social and governance factors may impose additional costs and expose us to new risks.

There is an increasing focus from certain investors, employees and other stakeholders concerning corporate responsibility, specifically related to environmental, social and governance factors. Some investors may use these factors to guide their investment strategies and, in some cases, may choose not to invest in us if they believe our policies relating to corporate responsibility are inadequate, including if they believe our policies relating to our Pledge 1% Movement commitment are inadequate. Third-party providers of corporate responsibility ratings and reports on companies have increased to meet growing investor demand for measurement of corporate responsibility performance. The criteria by which companies' corporate responsibility practices are assessed may change, which could result in greater expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. If we elect not to or are unable to satisfy such new criteria, investors may conclude that our policies with respect to corporate responsibility are inadequate. We may face reputational damage in the event that our corporate responsibility procedures or standards do not meet the standards set by various constituencies.

Furthermore, if our competitors' corporate responsibility performance is perceived to be greater than ours, potential or current investors may elect to invest with our competitors instead. In addition, in the event that we communicate certain initiatives and goals regarding environmental, social and governance matters, including with respect to the Pledge 1% Movement campaign, we could fail, or be perceived to fail, in our achievement of such initiatives or goals, or we could be criticized for the scope of such initiatives or goals. If we fail to satisfy the expectations of investors, employees and other stakeholders or our initiatives are not executed as planned, our reputation and financial results could be materially and adversely affected.

Risks Related to the Ownership of Our Common Stock

The trading price of our common stock is likely to be volatile and you could lose all or part of your investment.

The trading price of our common stock is likely to be volatile. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your shares of common stock at or above the initial public offering price. The market price for our common stock may be influenced by those factors discussed in this "Risk Factors" section and many other factors, including:

- timing and results of our preclinical studies and clinical trials or those of our competitors;
- the costs and timing of manufacturing for our product candidates, including developing our own manufacturing capabilities;
- the success of existing or new competitive therapies, products or technologies;
- development of new product candidates that may address our markets and make our product candidates less attractive;
- failure or discontinuation of any of our research or development programs;
- any termination or loss of rights under our GC Cell Research Services Agreement and our Master Agreement for Manufacturing Services with GC Cell;
- changes in the level of expenses related to any of our research or development programs;
- developments related to any existing or future collaborations;
- the recruitment or departure of key personnel;
- regulatory or legal developments in the United States and other countries;
- announcements by us, our partners or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- changes in the structure of healthcare payment systems;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- changes in failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- actual or expected changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- announcement or expectation of additional financing efforts;
- sales of common stock by us, our executive officers, directors or principal stockholders, or others;
- variations in our financial results or those of companies that are perceived to be similar to us;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions;
- changes in accounting principles; and
- the other factors described in this "Risk Factors" section and elsewhere in this Quarterly Report on Form 10-Q.

In addition, the stock market in general and the market for biopharmaceutical companies in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to operating performance of the particular companies affected. Following price volatility, holders of securities may institute securities class action litigation against the issuer. If any of holders of our common stock were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit and the attention of our board of directors and senior management would be diverted from the operation of our business. Any adverse determination in litigation could also subject us to significant liabilities. Further, a decline in the financial markets and related factors beyond our control may cause the price of our common stock to decline rapidly and unexpectedly. As a result of this volatility, investors may not be able to sell their common stock at or above the price at which they paid.

Our executive officers, directors and principal stockholders, if they choose to act together, will continue to have the ability to control or significantly influence all matters submitted to stockholders for approval.

Following the IPO, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned a significant percentage of our outstanding common stock. As a result, such persons, acting together, have the ability to significantly control or influence all matters submitted to our board of directors or stockholders for approval, including the appointment of our management, the election and removal of directors and approval of any significant transaction, as well as our management and business affairs. This concentration of ownership may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquiror from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders.

A significant portion of our total outstanding shares are eligible to be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of stockholders intend to sell shares of our common stock, could reduce the market price of our common stock. After our IPO, we had 23,281,561 shares of common stock outstanding. This includes the shares that we sold in our IPO, which may be resold in the public market immediately without restriction, unless purchased by our affiliates. Substantially all of the remaining 9,361,561 shares of common stock initially will be restricted as a result of securities laws, market standoff provisions or lock-up agreements, but will become eligible to be sold after IPO.

Moreover, certain of our stockholders have rights, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders, until such shares can otherwise be sold without restriction under Rule 144 under the Securities Act of 1933, as amended (the Securities Act), or until the rights terminate pursuant to the terms of the stockholders agreement between us and such holders. We also intend to register all shares of common stock subject to equity awards issued or reserved for future issuance under our equity compensation plans on a registration statement on Form S-8. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates under Rule 144 under the Securities Act and the market standoff provisions and lock-up agreements described above. Any sales of securities by these stockholders could have a negative impact on the trading price of our common stock.

Future sales and issuances of our securities, including pursuant to our equity incentive plans and our commitment to the Pledge 1% Movement, may cause dilution to our stockholders or decrease our stock price.

We expect that significant additional capital may be necessary to continue our planned operations, including for expanding product development, conducting clinical trials and commercializing our product candidates. We may seek additional capital through public or private equity or debt financings or other capital sources, which may include strategic collaborations and other strategic arrangements with third parties, to enable us to complete the development and potential commercialization of our product candidates. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder.

Pursuant to our 2024 Equity Incentive Plan (2024 Plan), our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. Additionally, the number of shares of our common stock reserved for issuance under our 2024 Plan will automatically increase on January 1 of each calendar year, beginning on January 1, 2025 and continuing through and including January 1, 2034, by 5% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors. In addition, pursuant to our ESPP, the number of shares of our common stock reserved for issuance will automatically increase on January 1 of each calendar year, beginning on January 1, 2025 (through January 1, 2034), by the lesser of (i) 1% of the total number of shares of our common stock outstanding on the last day of the calendar month before the date of the automatic increase, and (ii) 424,000 shares;

provided that before the date of any such increase, our board of directors may determine that such increase will be less than the amount set forth in clauses (i) and (ii). Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

Pursuant to our commitment to the Pledge 1% Movement campaign, in July 2021, our board of directors approved the reservation of up to 84,556 shares of our common stock (the Reserve) (which represented approximately 1.0% of our fully-diluted capitalization as of such date) that we may issue to or for the benefit of a charitable foundation established by us or other appropriate charitable recipients. The Reserve will be donated in equal installments over five years following our IPO or in full upon a sale of our company, in each case, first subject to certain per-share valuation thresholds for our common stock. We have not yet issued any of the Reserve. If any of the Reserve is issued pursuant to our Pledge 1% Movement commitment, such issuance may also dilute your ownership interest.

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

We are an "emerging growth company," as defined in the JOBS Act, and may remain an emerging growth company until the last day of the fiscal year following the fifth anniversary of the closing of our IPO. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenues exceed $1.24 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- 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" the JOBS Act allows us to delay adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements are made applicable to private companies.

We have taken advantage of the reduced reporting burdens and the information we provide to stockholders will be different than the information that is available with respect to other public companies that are not emerging growth companies. It is possible that this may cause investors to find our common stock less attractive. 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 reduced or more volatile.

Even following the termination of our status as an emerging growth company, we may be able to take advantage of the reduced disclosure requirements applicable to "smaller reporting companies," as that term is defined in Rule 12b-2 of the Exchange Act, and, in particular, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. To the extent that we are no longer eligible to use exemptions from various reporting requirements, we may be unable to realize our anticipated cost savings from these exemptions, which could have a material adverse impact on our operating results.

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

Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our reported financial position or results of operations. Financial accounting standards in the United States are constantly under review and new pronouncements and varying interpretations of pronouncements have occurred with frequency in the past and are expected to occur again in the future. As a result, we may be required to make changes in our accounting policies. Those changes could affect our financial condition and results of operations or the way in which such financial condition and results of operations are reported.

Compliance with new accounting standards may also result in additional expenses. As a result, we intend to invest all reasonably necessary resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from business activities to compliance activities. See the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Recent Accounting Pronouncements." As an emerging growth company, the JOBS Act allows us to delay adoption of new or revised accounting standards applicable to public companies until such pronouncements are made applicable to private companies. We have elected to use the extended transition period for complying with new or revised accounting standards and as a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates. However, we may elect to early adopt any new or revised accounting standards whenever such early adoption is permitted for non-public companies. We may take advantage of these exemptions up until the time that we are no longer an emerging growth company.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, would be your sole source of gain.

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. As a result, capital appreciation, if any, of our common stock would be your sole source of gain on an investment in our common stock for the foreseeable future.

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

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws, which are in effect, may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our amended and restated certificate of incorporation and amended and restated bylaws:

- permit our board of directors to issue up to 10,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate (including the right to approve an acquisition or other change in our control);
- provide that the authorized number of directors may be changed only by resolution of the board of directors;
- provide that the board of directors or any individual director may only be removed with cause and the affirmative vote of the holders of at least 66-2/3% of the voting power of all of our then outstanding common stock;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- divide our board of directors into three classes;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner and also specify requirements as to the form and content of a stockholder's notice;
- do not provide for cumulative voting rights, therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose; and
- provide that special meetings of our stockholders may be called only by the Chairman of the board, our Chief Executive Officer or by the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors.

The amendment of any of these provisions, with the exception of the ability of our board of directors to issue shares of preferred stock and designate any rights, preferences and privileges thereto, would require approval by the holders of at least 66-2/3% of our then-outstanding common stock.

In addition, as a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation Law (Section 203). These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a certain period of time. A Delaware corporation may opt out of this provision by express provision

in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of this provision.

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

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and any appellate court therefrom is 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 certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative claim or cause of action brought on our behalf; (ii) any claim or cause of action that is based upon a violation of a duty owed by any current or former director, officer, other employee or stockholder, to us or our stockholders; (iii) any claim or cause of action against us or any current or former director, officer or other employee, arising out of or pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws; (iv) any claim or cause of action seeking to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws (including any right, obligation, or remedy thereunder); (v) any claim or cause of action as to which the Delaware General Corporation Law confers jurisdiction on the Court of Chancery of the State of Delaware; and (vi) any claim or cause of action against us or any current or former director, officer or other employee, governed by the internal-affairs doctrine or otherwise related to our internal affairs, in all cases to the fullest extent permitted by applicable law and subject to the court having personal jurisdiction over the indispensable parties named as defendant; provided, however, that if the designation of such court as the sole and exclusive forum for a claim or action referred to in foregoing clauses (i) through (vi) would violate applicable law, then the United States District Court for the District of Delaware shall be the sole and exclusive forum for such claim or cause of action. These provisions would not apply to suits brought to enforce a duty or liability created by the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. Additionally, investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act, including all causes of action asserted against any defendant named in such complaint. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These choice of 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 and may discourage these types of lawsuits and result in increased costs for investors to bring a claim. If a court were to find the choice of forum provisions contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

General Risk Factors

We incur increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the Nasdaq listing requirements and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly, particularly after we no longer qualify as an

emerging growth company. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our board of directors.

We are evaluating these rules and regulations, and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404 of the Sarbanes-Oxley Act (Section 404) we are required to furnish a report by our management on our internal control over financial reporting beginning with our second filing of an Annual Report on Form 10-K with the SEC. However, while we remain an emerging growth company or smaller reporting company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants, adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing whether such controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. In addition, if we identify one or more material weaknesses as a result of this implementation and evaluation process, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Unstable market and economic conditions, including any adverse macroeconomic conditions or geopolitical events, may have serious adverse consequences on our business, financial condition and stock price.

The global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, rising inflation and monetary supply shifts, rising interest rates, supply chain constraints, labor shortages, declines in consumer confidence, declines in economic growth, increases in unemployment rates, recession risks and uncertainty about economic stability. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of public health crises, military conflict, including the conflict between Russia and Ukraine and the ongoing conflicts in the Middle East, terrorism or other geopolitical events. For example, the COVID-19 pandemic resulted in widespread unemployment, economic slowdown and extreme volatility in the capital markets. Sanctions imposed by the United States and other countries in response to military 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. The extent of the impact of these conditions on our operational and financial performance, including our ability to execute our business strategies and initiatives in the expected timeframe, as well as that of third parties upon whom we rely, will depend on future developments which are uncertain and cannot be predicted. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, 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. 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, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Section 404(a) of the Sarbanes-Oxley Act requires that beginning with our second annual report following our IPO, management assess and report annually on the effectiveness of our internal control over financial reporting and identify any material weaknesses in our internal control over financial reporting. Although Section 404(b) of the Sarbanes-Oxley Act requires our independent registered public accounting firm to issue an annual report that addresses the effectiveness of our internal control over financial reporting, we have opted to rely on the exemptions provided in the JOBS Act, and consequently will not be required to comply with SEC rules that implement Section 404(b) until such time as we are no longer an emerging growth company or smaller reporting company.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inadequate internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

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

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

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

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 biopharmaceutical 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. Additionally, the increase in the cost of directors' and officers' liability insurance may cause us to opt for lower overall policy limits or to forgo insurance that we may otherwise rely on to cover significant defense costs, settlements and damages awarded to plaintiffs.

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our common stock, our share price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not currently have, and may never obtain, research coverage by securities and industry analysts. If no or few securities or industry analysts commence coverage of us, the trading price for our shares could be negatively impacted. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our share performance, or if any of our preclinical studies or clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Our operations are concentrated in one location, and we or the third parties upon whom we depend may be adversely affected by a wildfire and earthquake or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our current operations are predominantly located in California. Any unplanned event, such as a flood, wildfire, explosion, earthquake, extreme weather condition, epidemic or pandemic, power outage, telecommunications failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Any similar impacts of natural or manmade disasters on our third-party contract manufacturing organizations (CMOs) and contract research organizations, or CROs, could cause delays in our clinical trials and may have a material and adverse effect on our ability to operate our business and have significant negative consequences on our financial and operating conditions. If a natural disaster, power outage or other event occurred that prevented us from using our clinical sites, impacted clinical supply or the conduct of our clinical trials, that damaged critical infrastructure, such as the manufacturing facilities of our third-party CMOs, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial

period of time. The disaster recovery and business continuity plans we and our CMOs and CROs have in place may prove inadequate in the event of a serious disaster or similar event. In the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance we currently carry will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our CMOs or CROs, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our development programs may be harmed. Any business interruption could adversely affect our business, financial condition, results of operations and prospects.

Our insurance policies may be inadequate, may not cover all of our potential liabilities and may potentially expose us to unrecoverable risks.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include property, general liability, employee benefits liability, business automobile, workers' compensation, clinical trials/products liability, cybersecurity liability, directors' and officers' and employment practices insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. No assurance can be given that an insurance carrier will not seek to cancel or deny coverage after a claim has occurred. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations. For example, although we maintain product liability insurance coverage that also covers our clinical trials, this insurance may not be adequate to cover all liabilities that we may incur, and we may be required to increase our product liability insurance coverage. We anticipate that we will need to increase our insurance coverage each time we commence a clinical trial and if we successfully commercialize any product candidate. Insurance availability, coverage terms and pricing continue to vary with market conditions. We endeavor to obtain appropriate insurance coverage for insurable risks that we identify. However, we may fail to correctly anticipate or quantify insurable risks, we may not be able to obtain appropriate insurance coverage and insurers may not respond as we intend to cover insurable events that may occur. Any significant uninsured liability may require us to pay substantial amounts, which would materially adversely affect our business, financial condition, results of operations and growth.

In addition, although we are dependent on certain key personnel, we do not have key person life insurance policies on any such individuals other than our Chief Executive Officer. While we maintain some life insurance coverage on our Chief Executive Officer, the insurance proceeds may not be sufficient to compensate for the adverse effects that we expect would arise from the loss of Fred Aslan, M.D., and the costs associated with recruiting a new Chief Executive Officer. Therefore, if any of our key personnel die or become disabled, the loss of such person could materially adversely affect our business, financial condition, results of operations and growth prospects.

Conflicts of interest may arise because some members of our board of directors are representatives of our principal stockholders.

Certain of our principal stockholders or their affiliates are venture capital funds or other investment vehicles that could invest in entities that directly or indirectly compete with us. As a result of these relationships, when conflicts arise between the interests of the principal stockholders or their affiliates and the interests of other stockholders, members of our board of directors that are representatives of the principal stockholders may not be disinterested.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about our clinical development programs and the diseases our product candidates are being developed to treat. We intend to utilize appropriate social media in connection with communicating about our development programs. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients may use social media channels to report an alleged adverse event during a clinical trial. When such disclosures occur, we may fail to monitor and comply with applicable adverse event reporting obligations, or we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our investigational products. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website, or a risk that a post on a social networking website by any of our employees may be construed as inappropriate promotion. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions, or incur other harm to our business.

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

Unregistered Sales of Equity Securities

Stock Option Awards

During the nine months ended September 30, 2024, we granted options to purchase an aggregate of 996,389 shares of our common stock at a weighted-average exercise price of $11.21 per share. The stock options were issued pursuant to written compensatory plans or arrangements with our employees and directors, in reliance on the exemption from the registration requirements provided by Rule 701 promulgated under the Securities Act or the exemption set forth in Section 4(a)(2) under the Securities Act and Rule 506 promulgated thereunder as a transaction not involving any public offering.

Common Stock Issued Upon Conversion of Preferred Stock

Immediately prior to the completion of the IPO, 6,160,385 outstanding shares of convertible preferred stock converted into 6,160,385 shares of common stock. Immediately prior to the completion of the IPO, we filed an Amended and Restated Certificate of Incorporation, which authorized a total of 700,000,000 shares of common stock and 10,000,000 shares of preferred stock. Upon the filing of the Amended and Restated Certificate of Incorporation, 6,160,385 shares of our convertible preferred stock then outstanding were automatically converted into 6,160,385 shares of our common stock. The issuance of such shares of our common stock was exempt from registration under Section 3(a)(9) or Section 4(2) of the Securities Act.

Common Stock Issued Upon Conversion of Simple Agreements for Future Equity (SAFEs)

In connection with the closing of the IPO, we had in aggregate approximately $24.4 million outstanding under our SAFEs, which converted to 2,391,418 shares of our common stock, based on the IPO price of $12.00 per share (IPO Price), at a 15% discount to the IPO Price.

Use of Proceeds

On July 22, 2024, we completed our IPO pursuant to which we issued and sold an aggregate of 13,920,000 shares of our common stock, at the IPO Price. In addition, we granted the underwriters a 30-day option to purchase up to an additional 2,088,000 shares of common stock at the public offering price, less underwriting discounts and commissions (Overallotment Option). On July 25, 2024, the underwriters exercised in-part their Overallotment Option and purchased 1,000,000 shares of our common stock. The offer and sale of all of the shares of our common stock in the IPO were registered under the Securities Act pursuant to our Registration Statement on Form S-1, as amended (File No. 333-280568), which were declared effective by the SEC on July 18, 2024. Jefferies LLC, TD Cowen and Cantor Fitzgerald & Co. acted as joint book-running managers for the IPO. Wedbush PacGrow and Needham & Company acted as co-lead managers for the IPO. Shares of our common stock began trading on The Nasdaq Global Market on July 19, 2024.

We received gross proceeds from our IPO of approximately $179.0 million, which resulted in net proceeds of approximately $162.3 million, after deducting underwriting discounts and commissions and other offering expenses payable by us. None of the underwriting discounts and commissions or other offering expenses were incurred or paid, directly or indirectly, to any of our directors or officers or their associates or to persons owning 10% or more of our common stock or to any of our affiliates.

There has been no material change in the planned use of proceeds from our IPO as described in the Prospectus that forms a part of our Registration Statement, which was filed with the SEC pursuant to Rule 424(b) on July 22, 2024.

Issuer Repurchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Trading Arrangements

During the last fiscal quarter, our directors and officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated the contracts, instructions or written plans for the purchase or sale of the Company's securities set forth in the table below:

			Type of Trading Arrangement			
Name and Position	**Action**	**Adoption/ Termination Date**	**Rule 10b5-1***	**Non-Rule 10b5-1****	**Total Shares of Common Stock to be Sold**	**Expiration Date**
Fred Aslan, M.D. (President, Chief Executive Officer and Director)	Adoption	July 23, 2024	X		471,558	December 31, 2026
Neha Krishnamohan (Chief Financial Officer and Executive Vice President of Corporate Development)	Adoption	July 23, 2024	X		12,768	June 2, 2027
Christopher Horan (Chief Technical Operations Officer)	Adoption	July 23, 2024	X		44,200	April 15, 2026
Thorsten Graef, M.D., Ph.D. (Chief Medical Officer)	Adoption	July 23, 2024	X		67,021	April 15, 2026
Jennifer Bush (Chief Operating Officer, Chief Legal Officer, Corporate Secretary and Compliance Officer)	Adoption	July 23, 2024	X		28,000	May 31, 2026
Heather Raymon, Ph.D. (Senior Vice President of Research and Early Development)	Adoption	July 23, 2024	X		25,434	April 15, 2026

* Contract, instruction or written plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act.

** "Non-Rule 10b5-1 trading arrangement" as defined in Item 408(c) of Regulation S-K under the Exchange Act.

Our directors and officers entered into lock-up agreements in connection with the IPO and they are not permitted to transfer, sell or otherwise dispose of securities under such plans during the lock-up period or pursuant to any exceptions set form in the lock-up agreements.

Item 6. Exhibits.

Exhibit number	Description of document	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	Amended and Restated Certificate of Incorporation.	8-K	7/22/2024	3.1	
3.2	Amended and Restated Bylaws.	S-1	6/28/2024	3.4	
4.1	Form of Common Stock Certificate of the Registrant.	S-1/A	7/15/2024	4.1	
4.2	Amended and Restated Investors' Rights Agreement, dated February 22, 2021, by and among the Registrant and certain of its stockholders.	S-1	6/28/2024	4.2	
10.1+	Form of Indemnity Agreement, by and between the Registrant and its directors and officers.	S-1	6/28/2024	10.1	
10.2+	The Registrant's 2024 Equity Incentive Plan	S-8	7/22/2024	99.3	
10.3+	Forms of Stock Option Grant Notice, Option Agreement and Notice of Exercise under the Registrant's 2024 Equity Incentive Plan.	S-1/A	7/15/2024	10.5	
10.4+	Forms of Restricted Stock Unit Grant Notice and Award Agreement under the Registrant's 2024 Equity Incentive Plan.	S-1/A	7/15/2024	10.6	
10.5+	The Registrant's 2024 Employee Stock Purchase Plan.	S-8	7/22/2024	99.6	
10.6+	The Registrant's Non-Employee Director Compensation Policy.	S-1/A	7/15/2024	10.8	
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 and 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				X
101.SCH	Inline XBRL Taxonomy Extension Schema With embedded Linkbase Documents Document				X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)				X

+ Indicates management contract or compensatory plan
* This certification is deemed not filed for purpose of section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

Signatures

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

ARTIVA BIOTHERAPEUTICS, INC.

Date: November 12, 2024

By: /s/ Fred Aslan, M.D.
Fred Aslan, M.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 12, 2024

By: /s/ Neha Krishnamohan
Neha Krishnamohan
Chief Financial Officer and EVP, Corporate Development
(Principal Financial Officer and Principal Accounting Officer)