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 ACT OF 1934**

For the transition period from _____ to _____

Commission file number: 000-22873

Oruka Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**36-3855489**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
855 Oak Grove Avenue **Suite 100** **Menlo Park, California**	**94025**
(Address of principal executive offices)	(Zip Code)

(650) 606-7910
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.001 per share	ORKA	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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes ☒ No ☐

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

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

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

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

As of October 31, 2024, there were 34,998,550 shares of the registrant's common stock outstanding.

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Part I - Financial Information

Item 1. Financial Statements

ORUKA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)
(In thousands, except share and per share data)

	September 30, 2024	February 6, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 410,875	$ —
Subscription receivable	—	1
Prepaid expenses and other current assets	2,074	—
Total current assets	412,949	1
Property and equipment, net	160	—
Operating lease right-of-use asset	938	—
Other non-current assets	43	—
Total assets	$ 414,090	$ 1
Liabilities, Convertible Preferred Stock and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,145	$ —
Accrued expenses and other current liabilities	1,710	—
Operating lease liability, current	146	—
Related party common stock warrant liability	7,681	—
Related party accounts payable and other current liabilities	6,357	—
Total current liabilities	18,039	—
Operating lease liability, non-current	842	—
Total liabilities	18,881	—
Commitment and contingencies (Note 11)		
Series A convertible preferred stock, $0.0001 par value; no shares and 20,000,000 shares authorized as of September 30, 2024 and February 6, 2024, respectively; no shares issued and outstanding as of September 30, 2024 and February 6, 2024; liquidation preference of $0 as of September 30, 2024 and February 6, 2024	—	—
Series A non-voting convertible preferred stock, $ 0.001 par value; 2,439 and no shares authorized as of September 30, 2024 and February 6, 2024, respectively; 2,439 and no shares issued and outstanding as of September 30, 2024 and February 6, 2024, respectively	52,841	—
Stockholders' equity:		
Series B non-voting convertible preferred stock, $ 0.001 par value; 251,504 and no shares authorized as of September 30, 2024 and February 6, 2024, respectively; 137,138 and no shares issued and outstanding as of September 30, 2024 and February 6, 2024, respectively	2,931	—
Common stock, $0.001 and $0.001 par value as of September 30, 2024 and February 6, 2024, respectively; 545,000,000 and 65,000,000 shares authorized, 34,998,550 and 3,197,975 shares issued and outstanding as of September 30, 2024 and February 6, 2024, respectively	35	—
Additional paid-in capital	397,345	1
Accumulated deficit	(57,943)	—
Total stockholders' equity	342,368	1
Total liabilities, convertible preferred stock and stockholders' equity	$ 414,090	$ 1

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

ORUKA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(UNAUDITED)
(In thousands, except share and per share data)

	Three Months Ended September 30, 2024	Period from February 6, 2024 (Inception) to September 30, 2024
Operating expenses		
Research and development[1]	$ 25,691	$ 49,557
General and administrative[2]	3,758	8,248
Total operating expenses	29,449	57,805
Loss from operations	(29,449)	(57,805)
Other income (expense)		
Interest income	1,330	1,330
Interest expense[3]	(504)	(1,468)
Total other income (expense), net	826	(138)
Net loss and comprehensive loss	$ (28,623)	$ (57,943)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.46)	$ (6.08)
Net loss per share attributable to Series A non-voting convertible preferred stockholders, basic and diluted	$ (1,461.10)	$ (6,077.25)
Net loss per share attributable to Series B non-voting convertible preferred stockholders, basic and diluted	$ (121.76)	$ (506.44)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	15,013,655	7,765,381
Weighted-average shares used in computing net loss per share attributable to Series A non-voting convertible preferred stockholders, basic and diluted	477	184
Weighted-average shares used in computing net loss per share attributable to Series B non-voting convertible preferred stockholders, basic and diluted	49,191	19,015

(1) Includes related party amount of $13,537 for the three months ended September 30, 2024 and $ 33,967 for the period from February 6, 2024 (inception) to September 30, 2024

(2) Includes related party amount of $71 for the three months ended September 30, 2024 and $ 1,339 for the period from February 6, 2024 (inception) to September 30, 2024

(3) Includes related party amount of $504 for the three months ended September 30, 2024 and $ 1,468 for the period from February 6, 2024 (inception) to September 30, 2024

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

ORUKA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(UNAUDITED)
(In thousands, except share data)

	Series A Convertible Preferred Stock		Series A Non-Voting Convertible Preferred Stock		Series B Non-Voting Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balances as of February 6, 2024 (inception)	—	$ —	—	—	—	$ —	3,197,975	$ 3	$ (2)	$ —	$ 1
Issuance of common stock	—	—	—	—	—	—	2,207,553	2	(2)	—	—
Issuance of Series A convertible preferred stock, net of issuance costs of $69	20,000,000	2,931	—	—	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	17	—	17
Net loss	—	—	—	—	—	—	—	—	—	(7,077)	(7,077)
Balances as of March 31, 2024	20,000,000	$ 2,931	—	—	—	—	5,405,528	$ 5	$ 13	$ (7,077)	$ (7,059)
Stock-based compensation expense	—	—	—	—	—	—	—	—	321	—	321
Net loss	—	—	—	—	—	—	—	—	—	(22,243)	(22,243)
Balances as of June 30, 2024	20,000,000	$ 2,931	—	—	—	—	5,405,528	$ 5	$ 334	$ (29,320)	$ (28,981)
Exchange of Series A convertible preferred stock for Series B non-voting convertible preferred stock upon the closing of the reverse recapitalization	(20,000,000)	(2,931)	—	—	137,138	2,931	—	—	—	—	2,931
Conversion of convertible notes (including accrued interest) into common stock upon the closing of the reverse recapitalization	—	—	—	—	—	—	2,722,207	3	26,445	—	26,448
Issuance of common stock and pre-funded warrants in the Pre-Closing Financing,	—	—	—	—	—	—	20,061,932	20	248,437	—	248,457
Issuance costs of Pre-Closing Financing and reverse recapitalization	—	—	—	—	—	—	—	—	(20,480)	—	(20,480)

Issuance of common stock to former stockholders of ARCA biopharma, Inc. in connection with the closing of the reverse recapitalization	—	—	—	—	—	—	1,208,883	1	4,999	—	5,000
Issuance of common stock, Series A non-voting convertible preferred stock, and pre-funded warrants in connection with the PIPE Financing	—	—	2,439	56,097	—	—	5,600,000	6	144,433	—	144,439
Issuance cost of PIPE Financing				(3,256)					(8,573)		(8,573)
Stock-based compensation expense									1,750		1,750
Net loss	—	—	—	—	—	—	—	—	—	(28,623)	(28,623)
Balances as of September 30, 2024	—	$ —	2,439	52,841	137,138	$ 2,931	34,998,550	$ 35	$ 397,345	$ (57,943)	$ 342,368

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

ORUKA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS
(UNAUDITED)
(In thousands)

	Period from February 6, 2024 (Inception) to September 30, 2024
Cash flows from operating activities:	
Net loss	$ (57,943)
Adjustments to reconcile net loss to net cash used in operating activities:	
Depreciation expense	11
Stock-based compensation expense	9,769
Non-cash interest expense	1,468
Non-cash lease expense	65
Changes in operating assets and liabilities:	
Prepaid expenses and other current assets	(1,980)
Other non-current assets	(43)
Accounts payable	1,621
Accrued expenses and other current liabilities	1,650
Operating lease liability	6
Related party accounts payable and other current liabilities	6,357
Net cash used in operating activities	(39,019)
Cash flows from investing activities:	
Purchases of property and equipment	(171)
Net cash used in investing activities	(171)
Cash flows from financing activities:	
Proceeds from issuance of Pre-Merger Oruka Series A Preferred Stock, net of issuance costs paid	2,931
Proceeds from issuance of notes payable to related parties, net of issuance costs paid	24,980
Proceeds from the Pre-Closing Financing, net	228,127
Proceeds from the PIPE Financing, net	189,087
Cash acquired in connection with the reverse recapitalization	4,940
Net cash provided by financing activities	450,065
Net increase in cash and cash equivalents	410,875
Cash at beginning of period	-
Cash and cash equivalents at end of period	$ 410,875
Supplemental disclosure of non-cash operating and financing activities:	
Operating lease liability arising from obtaining operating right-of-use asset	$ 982
Assets acquired in connection with the reverse recapitalization	$ 114
Other liabilities assumed in connection with the reverse recapitalization	$ (54)
Pre-Closing Financing and reverse recapitalization issuance costs included in accounts payable	$ 150
PIPE Financing issuance costs included in accounts payable	$ 374
PIPE Financing issuance costs included in accrued expenses and other current liabilities	$ 6
Non-cash accrued interest on convertible note converted to common stock	$ 1,468
Non-cash exchange of Pre-Merger Oruka Series A Preferred Stock for Company Series B Convertible Preferred Stock	$ 2,931

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

ORUKA THERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

1. Nature of the Business and Basis of Presentation

Background and Basis of Presentation

Oruka Therapeutics, Inc., together with its subsidiaries (collectively, the "Company"), formerly known as ARCA biopharma, Inc. ("ARCA"), is an early-stage biotechnology company that is the result of the reverse recapitalization discussed below. Prior to the reverse recapitalization, the private company Oruka Therapeutics, Inc. ("Pre-Merger Oruka") was established and incorporated under the laws of the state of Delaware on February 6, 2024 (referred to in the Notes as the inception of the Company). The Company is headquartered in Menlo Park, California. The Company is focused on developing biologics to optimize the treatment of inflammatory skin diseases.

These condensed consolidated financial statements reflect, in the opinion of management, all adjustments of a normal and recurring nature that are necessary for a fair statement of the Company's financial position as of September 30, 2024, and its results of operations for the three months ended September 30, 2024 and from February 6, 2024 (inception) to September 30, 2024, and cash flows for the period from February 6, 2024 (inception) to September 30, 2024. The condensed balance sheet as of February 6, 2024, included in the condensed consolidated balance sheets was derived from the Company's audited financial statements. The condensed consolidated financial statements and accompanying notes are prepared in accordance with United States ("U.S.") generally accepted accounting principles ("GAAP") for interim financial reporting and the rules and regulations of the U.S. Securities and Exchange Commission (the "SEC") and therefore do not include all information and disclosures normally included in the annual consolidated financial statements.

The results for the three months ended September 30, 2024 and the period from February 6, 2024 (inception) to September 30, 2024 are not necessarily indicative of results expected for the full fiscal year or any subsequent interim period. The condensed consolidated financial statements include the financial statements of its wholly-owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

Reverse Recapitalization and Pre-Closing Financing

On August 29, 2024, the Company consummated the previously announced business combination ("Closing") pursuant to that certain Agreement and Plan of Merger and Reorganization, dated April 3, 2024 (the "Merger Agreement"), by and among ARCA, Atlas Merger Sub Corp, a wholly owned subsidiary of ARCA ("First Merger Sub"), Atlas Merger Sub II, LLC, a wholly owned subsidiary of ARCA ("Second Merger Sub") and Pre-Merger Oruka, pursuant to which, among other matters, Pre-Merger Oruka merged with and into First Merger Sub, with Pre-Merger Oruka continuing as a wholly owned subsidiary of ARCA and the surviving corporation of the merger ("First Merger") and following that, Pre-Merger Oruka then merged with and into Second Merger Sub, with Second Merger Sub being the surviving entity of the second merger (the "Second Merger" and together with the First Merger, the "Merger"). Following consummation of the Merger, the Company effected a 1-for-12 reverse stock split (the "Reverse Stock Split") of the common stock, par value $0.001 per share, of the Company ("Company Common Stock"), which became effective on September 3, 2024. The Company Common Stock commenced trading on a post-Reverse Stock Split, post-Merger basis at the opening of trading on September 3, 2024. Second Merger Sub changed its corporate name to "Oruka Therapeutics Operating Company, LLC" and ARCA changed its name to "Oruka Therapeutics, Inc." The Company is led by the Pre-Merger Oruka management team and remains focused on developing biologics to optimize the treatment of inflammatory skin diseases.

Immediately prior to the execution and delivery of the Merger Agreement on April 3, 2024, certain new and existing investors of Pre-Merger Oruka entered into a subscription agreement with Pre-Merger Oruka (the "Subscription Agreement"), pursuant to which, and on the terms and subject to the conditions of which, immediately prior to the Closing, those investors purchased shares of common stock of Pre-Merger Oruka ("Pre-Merger Oruka Common Stock") and Pre-Merger Oruka pre-funded warrants for gross proceeds of approximately $275.0 million (which includes $ 25.0 million of proceeds previously received from the issuance of the Convertible Note (as defined in Note 6) and accrued interest on such note which converted to shares of Pre-Merger Oruka Common Stock) (the "Pre-Closing Financing"). The Company incurred transaction costs of $20.5 million which was recorded as a reduction to additional paid-in capital in the unaudited condensed consolidated financial statements. At the Closing, the shares of Pre-Merger Oruka Common Stock and Pre-Merger Oruka pre-funded warrants issued pursuant to the Subscription Agreement were converted into shares of Company Common Stock and pre-funded warrants of Company Common Stock in accordance with the Exchange Ratio (defined below).

In accordance with an Exchange Ratio determined by terms of the Merger Agreement and upon the effective time of the First Merger (the "First Effective Time"), (i) each then-issued and outstanding share of Pre-Merger Oruka Common Stock including outstanding and unvested Pre-Merger Oruka restricted stock and shares of Pre-Merger Oruka Common Stock issued in connection with the Subscription Agreement, were converted into the right to receive a number of shares of Company Common Stock, equal to the Exchange Ratio of 6.8569 shares of Company Common Stock, which were subject to the same vesting provisions as those immediately prior to the Merger, (ii) each share of Pre-Merger Oruka Series A convertible preferred stock, par value $0.0001 ("Pre-Merger Oruka Series A Preferred Stock"), outstanding immediately prior to the First Effective Time was converted into the right to receive a number of shares of ARCA Series B non-voting convertible preferred stock, par value $0.001 per share ("Company Series B Preferred Stock"), which are convertible into shares of Company Common Stock, at a conversion ratio of approximately 83:3332:1 (iii) each outstanding option to purchase Pre-Merger Oruka Common Stock was converted into an option to purchase shares of Company Common Stock, (iv) each outstanding warrant to purchase shares of Pre-Merger Oruka Common Stock was converted into a warrant to purchase shares of Company Common Stock, and (v) each share of Company Common Stock issued and outstanding at the First Effective Time remain issued and outstanding in accordance with its terms and such shares. Subsequent to the close of the merger, the common stock shares were then, subject to the reverse stock split of 1-for-12 effected on September 3, 2024. Net loss per share for periods prior to the close of the reverse recapitalization has been revised to reflect the exchange ratio. After applying the exchange ratio and the reverse stock split, net loss per share for the periods from February 6, 2024 (inception) to March 31, 2024 and for three months ended June 30, 2024 and from February 6, 2024 (inception) to June 30, 2024 are $(2.21), $(6.96), and $(9.17), respectively.

As part of the Pre-Closing Financing and the Closing, investors in the Pre-Closing Financing received 22,784,139 shares of Company Common Stock in exchange for 39,873,706 shares of Pre-Merger Oruka Common Stock (which includes the issuance of 2,722,207 shares of Company Common Stock in exchange for 4,764,032 shares of Pre-Merger Oruka Common Stock on the conversion of Convertible Note along with the accrued interest through the conversion date) and 5,522,207 Company pre-funded warrants in exchange for 9,664,208 Pre-Merger pre-funded warrants.

The Merger was accounted for as a reverse recapitalization in accordance with U.S. GAAP. Under this method of accounting, Pre-Merger Oruka was deemed to be the accounting acquirer for financial reporting purposes. This determination was primarily based on the fact that, immediately following the Merger: (i) Pre-Merger Oruka stockholders own a substantial majority of the voting rights in the combined company; (ii) Pre-Merger Oruka's largest stockholders retain the largest interest in the combined company; (iii) Pre-Merger Oruka designated a majority of the initial members of the board of directors of the combined company; and (iv) Pre-Merger Oruka's executive management team became the management team of the combined company. Accordingly, for accounting purposes: (i) the Merger was treated as the equivalent of Pre-Merger Oruka issuing stock to acquire the net assets of ARCA, and (ii) the reported historical operating results of the combined company prior to the Merger are those of Pre-Merger Oruka. Additional information regarding the Merger is included in Note 3.

Reverse Stock Split

On September 3, 2024, the Company effected the Reverse Stock Split, a 1-for-12 reverse stock split of Company Common Stock. The par value per share and the number of authorized shares were not adjusted as a result of the Reverse Stock Split. The shares of Company Common Stock underlying outstanding stock options, common stock warrants and other equity instruments were proportionately reduced and the respective exercise prices, if

applicable, were proportionately increased in accordance with the terms of the agreements governing such securities. All references to common stock, options to purchase common stock, outstanding common stock warrants, common stock share data, per share data, and related information contained in the condensed consolidated financial statements have been retrospectively adjusted to reflect the effect of the Reverse Stock Split for all periods presented, unless otherwise specifically indicated or the context otherwise requires.

PIPE Financing

On September 11, 2024, the Company entered into a Securities Purchase Agreement for a private placement (the "PIPE Financing") with certain institutional and accredited investors. The closing of the PIPE Financing occurred on September 13, 2024.

Pursuant to the Securities Purchase Agreement, the investors purchased an aggregate of 5,600,000 shares of Company Common Stock at a purchase price of $23.00 per share, an aggregate of 2,439 shares of the Company's Series A non-voting convertible preferred stock, par value $ 0.001 per share ("Company Series A Preferred Stock"), at a purchase price of $23,000.00 per share (each Company Series A Preferred Stock is convertible into 1,000 shares of Company Common Stock), and pre-funded warrants to purchase an aggregate of 680,000 shares of Company Common Stock at a purchase price of $22.999 per pre-funded warrant, for aggregate net proceeds of approximately $ 188.7 million (net of issuance costs of $ 11.8 million).

Liquidity and Going Concern

Since its inception, the Company has devoted substantially all of its resources to advancing the development of its portfolio of programs, organizing and staffing the Company, business planning, raising capital, and providing general and administrative support for these operations. Current and future programs will require significant research and development efforts, including preclinical and clinical trials, and regulatory approvals to commercialization. Until such time as the Company can generate significant revenue from product sales, if ever, the Company expects to finance its operating activities through a combination of equity offerings and debt financings.

The Company has not generated any revenue from product sales or other sources and has incurred significant operating losses and negative cash flows from operations since inception. The Company has incurred a net loss of $28.6 million for the three months ended September 30, 2024 and $57.9 million during the period from February 6, 2024 (inception) to September 30, 2024. For the period from February 6, 2024 (inception) to September 30, 2024, the Company used net cash of $39.0 million for its operating activities.

As of September 30, 2024, the Company had cash and cash equivalents of $ 410.9 million. The Company's management expects that the existing cash and cash equivalents will be sufficient to fund the Company's operating plans for at least twelve months from the date these condensed consolidated financial statements were issued. The Company expects that its research and development and general and administrative costs will continue to increase significantly, including in connection with conducting future pre-clinical activities and clinical trials and manufacturing for its existing product candidates and any future product candidates to support commercialization and providing general and administrative support for its operations, including the costs associated with operating as a public company. The Company's ability to access capital when needed is not assured and, if capital is not available to the Company when, and in the amounts needed, the Company may be required to significantly curtail, delay or discontinue one or more of its research or development programs or the commercialization of any product candidate, or be unable to expand its operations or otherwise capitalize on the Company's business opportunities, as desired, which could materially harm the Company's business, financial condition and results of operations.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of the Company's condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates, assumptions, and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent liabilities at the date of the condensed consolidated financial statements and the reported amounts of income and expenses during the reporting periods. Significant estimates and assumptions reflected within these condensed consolidated financial statements include but are not limited to research and development expenses and related prepaid or accrued costs and the valuation of stock-based compensation awards and related expenses. The Company bases its estimates on known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates, as there are changes in circumstances, facts, and experience. Actual results could differ materially from those estimates or assumptions.

Concentrations of Credit Risk and Other Risks and Uncertainties

The Company's cash and cash equivalents are maintained with financial institutions in the United States of America. Cash balances are held at financial institutions and account balances may exceed federally insured limits. To date, the Company has not experienced any losses on its cash and cash equivalents and periodically evaluates the creditworthiness of its financial institutions.

The Company manages credit risk associated with its investment portfolio through its investment policy, which limits investments to high-quality issuers and limits the amount of its portfolio that can be invested in a single issuer.

The Company is dependent on third-party organizations to research, develop, manufacture, and process its product candidates for its development programs, including its two most advanced programs, ORKA-001 and ORKA-002. The Company expects to continue to be dependent on a small number of manufacturers to supply it with its requirements for all products. The Company's research and development programs could be adversely affected by a significant interruption in the supply of the necessary materials. A significant amount of the Company's research and development activities are performed under its agreements with Paragon Therapeutics, Inc. ("Paragon") (see Note 10).

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less at the time of initial purchase to be cash equivalents. The cash equivalents were comprised of investments in money market funds.

Debt Issuance Costs

Debt issuance costs incurred in connection with the Convertible Note (see Note 6) are recorded as a reduction of the carrying value of the notes

payable liability on the Company's balance sheet and are amortized to interest expense over the term of the loan using the effective interest method.

Subscription Receivable

The Company accounts for any notes received in exchange for common stock as a subscription receivable, provided the note underlying the receivable is paid prior to the date the financial statement is available to be issued.

Fair Value Measurements

Certain assets and liabilities are carried at fair value under U.S. GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1 — Quoted prices in active markets that are identical assets or liabilities.
- Level 2 — Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3 — Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies, and similar techniques.

The Company's cash equivalents are carried at fair value, determined according to the fair value hierarchy described above (see Note 4). The carrying values of the Company's prepaid expenses and other current assets, accounts payable and accrued expenses and other current liabilities approximate their fair values due to their relatively short maturity period.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation expense is recognized using the straight-line method over the estimated useful life of each asset as follows:

	Estimated Useful Life
Furniture and fixtures	3-5 years
Computer and office equipment	3-5 years

Classification of Convertible Preferred Stock

Prior to the reverse recapitalization, the Company had classified its Pre-Merger Oruka Series A Preferred Stock outside of stockholders' equity (deficit) on the Company's condensed consolidated balance sheet because the holders of such stock have certain liquidation rights in the event of a deemed liquidation event that, in certain situations, is not solely within the control of the Company and would require the redemption of the then-outstanding convertible preferred stock.

Upon the closing of the Merger, the Company converted its Pre-Merger Oruka Series A Preferred Stock to Company Series B Preferred Stock and has classified the Company Series B Preferred Stock within stockholders' equity (deficit) on its condensed consolidated balance sheet because the Company Series B Preferred Stock is not redeemable or puttable to the Company by the holder under any circumstances.

In connection with the PIPE Financing (see Note 1) the Company issued Company Series A Preferred Stock, and has classified the Company Series A Preferred Stock outside of stockholders' equity (deficit) on the Company's condensed consolidated balance sheet because the holders of such stock have certain rights (see Note 7) that, in certain situations, is not solely within the control of the Company and would require the redemption of the then-outstanding convertible preferred stock.

Note Payable to Related Party

The Company accounted for the Convertible Note (as defined in Note 6) at amortized cost. The Company considered if optional conversion features are required to be bifurcated and separately accounted for as a derivative. Costs related to the issuance of the Convertible Note were recorded as a debt discount, amortized over the term of the Convertible Note (see Note 6) and were accounted as interest expense in other income (expenses) within the condensed consolidated statements of operations and comprehensive loss using the effective interest method. At the effective time of the Merger, shares of Pre-Merger Oruka Common Stock issued pursuant to the conversion of the Convertible Note (including accrued interest) automatically converted into shares of Company Common Stock (see Note 1).

Research and Development Contract Costs Accruals

The Company records the costs associated with research studies and manufacturing development as incurred. These costs are a significant component of the Company's research and development expenses, with a substantial portion of the Company's ongoing research and development activities conducted by third-party service providers, including contract research organizations ("CROs") and contract manufacturing organizations ("CMOs"), and the Company's related-party Paragon (see Note 10).

The Company accrues for expenses resulting from obligations under its two antibody discovery and option agreements (the "Option Agreements") (see Note 10), by and among Paragon, Paruka Holding LLC ("Paruka"), an entity formed by Paragon as a vehicle to hold equity in the Company, and the Company as well as agreements with CROs, CMOs, and other outside service providers for which payment flows do not match the periods over which materials or services are provided to the Company. Accruals are recorded based on estimates of services received and efforts expended pursuant to agreements established with Paragon, CROs, CMOs, and other outside service providers. These estimates are typically based on contracted amounts applied to the proportion of work performed and determined through analysis with internal personnel and external service providers as to the progress or stage of completion of the services. The Company makes significant judgments and estimates in determining the accrual balance in each reporting period. If advance payments are made to Paragon, a CRO, CMO, or outside service provider, the payments will be recorded as a prepaid asset which will be expensed as the contracted services are performed. Changes in these estimates that result in material changes to the Company's accruals could materially affect the Company's results of operations. As of September 30, 2024, the Company has not experienced any material deviations between accrued and actual research and development expenses.

Leases

At the lease commencement date, when control of the underlying asset is transferred from the lessor to the Company, the Company classifies a lease as either an operating or finance lease and recognizes a right-of-use ("ROU") asset and a current and non-current lease liability, as applicable, in the balance sheet if the lease has a term greater than one year. Lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise its option.

At the lease commencement date, operating lease liabilities and their corresponding ROU assets are recorded at the present value of future minimum lease payments over the expected remaining lease term. The Company determines the present value of lease payments using the implicit rate, if it is readily determinable, or the risk-free discount rate for a period comparable with that of the lease term. For operating leases, lease expense for lease payments is recognized on a straight-line basis over the lease term. For finance leases, lease expense includes amortization expense of the ROU asset recognized on a straight-line basis over the lease term and interest expense recognized on the finance lease liability. In addition, certain adjustments to the ROU asset may be required for items such as lease prepayments, incentives received or initial direct costs. As of September 30, 2024, the Company has one operating lease and no finance leases.

The Company accounts for lease and non-lease components related to operating leases as a single lease component. The Company has elected that costs associated with leases having an initial term of 12 months or less are recognized in the condensed consolidated statement of operations and comprehensive loss on a straight-line basis over the lease term and are not recorded on its condensed consolidated balance sheets. Variable lease expense is recognized as incurred and consists primarily of real estate taxes, utilities, and other office space related expenses.

Segment Reporting

The Company operates and manages its business as a single segment for the purposes of assessing performance and making operating decisions. The Company's chief executive officer, who is the chief operating decision maker (the "CODM"), reviews the Company's financial information on an aggregated basis for purposes of evaluating financial performance and allocating resources.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development costs include salaries and bonuses, stock-based compensation, employee benefits, and external costs of vendors and consultants engaged to conduct research and development activities, as well as allocated human resource costs, information technology costs, and facility-related costs, including rent, maintenance, utilities, and depreciation.

Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses on the accompanying condensed consolidated balance sheet. The prepaid amounts are expensed as the related goods are delivered or the services are performed, or when it is no longer expected that the goods will be delivered, or the services rendered. If nonrefundable advance payments represent a one-time cost for obtaining goods or services, with anticipated benefits to be utilized within a year of period end, the payment is expensed immediately.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and bonuses, stock-based compensation, employee benefits, finance and administration costs, patent and intellectual property costs, professional fees, as well as allocated human resource costs, information technology costs, and facility-related costs, including rent, maintenance, utilities and depreciation.

Commitments and Contingencies

The Company is subject to contingent liabilities, such as legal proceedings and claims, that arise in the ordinary course of business activities. The Company accrues for loss contingencies when losses become probable and are reasonably estimable. If the reasonable estimate of the loss is a range and no amount within the range is a better estimate, the minimum amount of the range is recorded as a liability on the balance sheet. The Company does not accrue for contingent losses that, in its judgment, are considered to be reasonably possible, but not probable; however, it discloses the range of reasonably possible losses. As of September 30, 2024, no liabilities were recorded for loss contingencies (see Note 11).

Stock-Based Compensation

The Company measures all stock-based awards granted to employees, directors, and non-employees in the form of stock options to purchase shares of its common stock, based on the fair value of the awards on the date of grant using the Black-Scholes option-pricing model. The Company measures restricted common stock awards ("RSAs") using the difference, if any, between the purchase price per share of the award and the fair value of the Company's common stock at the date of grant.

The Company grants stock options, restricted stock awards, and warrants that are subject to service or performance-based vesting conditions. Compensation expense for awards to employees and directors with service-based vesting conditions is recognized using the straight-line method over the requisite service period, which is generally the vesting period of the respective award. Compensation expense for awards to non-employees with service-based vesting conditions is recognized in the same manner as if the Company had paid cash in exchange for the goods or services, which is generally over the vesting period of the award. Forfeitures are accounted for as they occur. As of each reporting date, the Company estimates the probability that specified performance criteria will be met and does not recognize compensation expense until it is probable that the performance-based vesting condition will be achieved.

The Company has issued stock options, warrants, and RSAs with service-based and performance-based vesting conditions.

The Company recognizes the compensation expense for the option to purchase common stock under the Employee Stock Purchase Plan ("ESPP"), based on the fair value of the common stock estimated using the closing price of the Company's common stock as reported on the date of offering, less the purchase discount percentage provided for in the plan.

The Company classifies stock-based compensation expense in its condensed consolidated statement of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

Net Loss per Share Attributable to Stockholders

Basic and diluted net loss attributable to stockholders per share is presented in conformity with the two-class method required for participating securities (Pre-Merger Oruka Series A Preferred Stock). Basic earnings per share is computed by dividing net income available to each class of shares by the weighted-average number of shares of common stock and participating securities outstanding during the period. Pre-funded warrants were included

as the exercise price is negligible and these warrants are fully vested and exercisable. Company Series A Preferred Stock and Company Series B Preferred Stock share the same characteristics as Common Stock and have no substantive preference attributed to them and, accordingly, have been considered as classes of Common Stock in the computation of net loss per share regardless of their legal form.

Net loss is allocated to common stock based on its proportional ownership on an as-converted basis. Net loss is not allocated to participating securities as they do not have an obligation to fund losses. The weighted-average number of shares outstanding of common stock reflects changes in ownership over the periods presented. See Note 7— Convertible Preferred Stock and Stockholders' Equity.

Diluted net loss per share is computed by dividing the net loss attributable to stockholders adjusted for income (expenses), net of tax, related to any diluted securities, by the weighted-average number of shares of common stock and potentially dilutive securities outstanding for the period. For purposes of this calculation, stock options to purchase common stock, employee warrants to purchase common stock, and unvested RSAs are considered potential dilutive common shares.

The Company generated a net loss for the periods presented. Accordingly, basic and diluted net loss per share is the same because the inclusion of the potentially dilutive securities would be anti-dilutive.

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the financial statements or in the Company's tax returns. Deferred tax assets and liabilities are determined based on the differences between the financial statement basis and tax basis of assets and liabilities using enacted tax rates in effect for the years in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. The potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in the condensed consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more likely than not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the condensed consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties. The Company had accrued no amounts for interest or penalties related to uncertain tax positions as of September 30, 2024.

Recently Issued Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* ("ASU 2023-07"), which enhances the segment disclosure requirements for public entities on an annual and interim basis. Under this proposal, public entities will be required to disclose significant segment expenses that are regularly provided to the CODM and included within each reported measure of segment profit or loss. Additionally, current annual disclosures about a reportable segment's profit or loss and assets will be required on an interim basis. Entities will also be required to disclose information about the CODM's title and position at the Company along with an explanation of how the CODM uses the reported measures of segment profit or loss in their assessment of segment performance and deciding how to allocate resources. Finally, ASU 2023-07 requires all segment disclosures for public entities that have only a single reportable segment. The amendments in ASU 2023-07 are effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. The Company is currently evaluating the impact of the adoption of this ASU on its consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* . This ASU expands disclosures in an entity's income tax rate reconciliation table and disclosures regarding taxes paid both in the U.S. and foreign jurisdictions. This update is effective beginning with the Company's 2025 fiscal year annual reporting period. The Company is currently evaluating the impact of the adoption of this ASU on its consolidated financial statements.

In November 2024, the FASB issued ASU 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*. This ASU requires more detailed disclosures, on an annual and interim basis, about specified categories of expenses (including employee compensation, depreciation, and amortization) included in certain expense captions presented on the face of the income statement. This ASU is effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. This ASU may be applied either prospectively or retrospectively. The Company is currently evaluating the impact of the adoption of this ASU on its consolidated financial statements.

3. Reverse Recapitalization and Pre-Closing Financing

As described within the *Reverse Recapitalization and Pre-Closing Financing* section in Note 1, on August 29, 2024, the reverse recapitalization between Pre-Merger Oruka and ARCA was consummated. The Merger was accounted for as a reverse recapitalization in accordance with U.S. GAAP. At the effective time of the Merger, substantially all of the assets of ARCA consisted of cash and cash equivalents and other nominal non-operating assets and liabilities. No goodwill or intangible assets were recognized.

As part of the recapitalization, the Company acquired the assets and liabilities listed below (in thousands):

	Amount
Cash and cash equivalents	$ 4,940
Other current assets	114
Accrued liabilities	(54)
Net assets acquired	$ 5,000

4. Fair Value Measurements

The following tables present the Company's fair value hierarchy for financial assets measured as of September 30, 2024 (in thousands):

	Fair Value Measurements as of September 30, 2024			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds	$ 403,322	$ —	$ —	$ 403,322
Total financial assets	$ 403,322	$ —	$ —	$ 403,322

There were no transfers between Level 1, Level 2, or Level 3 during the period from February 6, 2024 (inception) to September 30, 2024.

5. Accrued Expenses and Other Current Liabilities

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

	September 30, 2024
Accrued employee compensation and benefits	$ 933
Accrued professional and consulting	204
Accrued research and development	573
	$ 1,710

6. Note Payable with Related Party

In March 2024, the Company entered into a Series A Preferred Stock and Convertible Note Purchase Agreement (the "Purchase Agreement") with Fairmount Healthcare Fund II, L.P. ("Fairmount"), whereby the Company issued a convertible note (the "Convertible Note"), with an initial principal amount of $25.0 million that, at the time of issuance, could be converted into Pre-Merger Oruka Series A Preferred Stock (or a series of preferred shares that is identical in respect to the shares of preferred shares issued in its next equity financing) or shares of Pre-Merger Oruka Common Stock in exchange for aggregate proceeds of $25.0 million. The Convertible Note accrued interest at a rate of 12.0% per annum. At issuance, the Convertible Note required all unpaid interest and principal to mature on December 31, 2025 (the "Maturity Date") and prepayment was not permitted without prior written consent of Fairmount. At issuance, the principal payment along with the accrued interest on the Convertible Note was due in full on the Maturity Date.

The Company assessed all terms and features of the Convertible Note in order to identify any potential embedded features that would require bifurcation. As part of this analysis, the Company assessed the economic characteristics and risks of the embedded features. The Company determined that the share settled redemption feature was clearly and closely related to the debt host and did not require separate accounting. The Company determined that the conversion options of the Convertible Note were not clearly and closely associated with a debt host. However, these features did not meet the definition of a derivative under ASC 815, *Derivatives and Hedging*, and as a result, did not require separate accounting as a derivative liability.

The Company paid debt issuance costs of less than $ 0.1 million in relation to the Convertible Note. The debt issuance costs were reflected as a reduction of the carrying value of Convertible Note on the condensed consolidated balance sheet and were being amortized as interest expense over the term of the Convertible Note using the effective interest method. For the three months ended September 30, 2024 and the period from February 6, 2024 (inception) to September 30, 2024, the Company recognized interest expenses related to the Convertible Note of $0.5 million and $ 1.5 million, respectively, which includes non-cash interest expense related to the amortization of debt issuance.

Immediately prior to the completion of the Merger (see Note 1), the Convertible Note was converted into shares of Pre-Merger Oruka Common Stock based on the aggregate principal amount of $25.0 million, plus unpaid accrued interest of $ 1.5 million divided by the conversion price which was determined based upon the Company's fully-diluted capitalization immediately prior to the Merger. At the effective time of the Merger, the Pre-Merger Oruka Common Stock issued upon the conversion of the Convertible Note (including accrued interest) automatically converted into 2,722,207 shares of Company Common Stock. As of September 30, 2024, the Convertible Note is not outstanding.

7. Convertible Preferred Stock and Stockholders' Equity

Pre-Funded Warrants

In August 2024, pursuant to the Subscription Agreement and immediately prior to the Closing, certain new and current investors purchased pre-funded warrants, which, at the effective time of the Merger, were exercisable for 5,522,207 shares of Company Common Stock at a purchase price of approximately $9.70 per warrant. After the Merger, there are 5,522,207 pre-funded warrants outstanding and are exercisable for 5,522,207 shares of the Company Common Stock at an exercise price of $0.01 per share.

In September 2024, in connection with the PIPE Financing, the Company issued and sold 680,000 pre-funded warrants, at a purchase price of $22.999 per warrant, exercisable for 680,000 shares of Company Common Stock at an exercise price of $ 0.001 per share.

The pre-funded warrants were recorded as a component of stockholders' equity within additional paid-in-capital and have no expiration date. As of September 30, 2024, none of the pre-funded warrants have been exercised and 6,202,207 pre-funded warrants remain outstanding.

Employee Warrants

In July 2024, Pre-Merger Oruka entered into a Subscription Agreement that provided for, among other things, the issuance of warrants to certain of Pre-Merger Oruka's employees, directors, and service providers immediately prior to the closing of the Merger. During the three months ended September 30, 2024, 3,054,358 employee warrants were issued at an exercise price of $ 7.80 per warrant. These employee warrants vest over a period of four years. Per the terms of the Employee Warrant Agreement, the holders of the Company's employee warrants shall not have any of the rights or privileges of a stockholder of the Company in respect of any shares purchasable upon the exercise of the warrant or any portion thereof unless and until a certificate or certificates representing such shares have been issued or a book entry representing such shares has been made and such shares have been deposited with the appropriate registered book-entry custodian. The Company recognizes compensation cost related to employee warrants on a straight-line basis over the requisite service period, which is the period in which the related services are received. As of September 30, 2024, none of the employee warrants have been exercised and 3,054,358 employee warrants remain outstanding.

Convertible Preferred Stock

In March 2024, Pre-Merger Oruka issued and sold an aggregate of 20,000,000 shares of Pre-Merger Oruka Series A Preferred Stock to Fairmount (see Note 13), at a purchase price of approximately $0.15 per share, for aggregate gross proceeds of $3.0 million. Pre-Merger Oruka incurred less than $0.1 million of issuance costs in connection with this transaction. Upon the issuance of the Pre-Merger Oruka Series A Preferred Stock, the Company assessed the embedded conversion and liquidation features of the securities as described below and determined that such features did not require the Company to separately account for these features.

In August 2024, upon the closing of the Merger, the Company converted the Pre-Merger Oruka Series A Preferred Stock to 137,138 shares of Company Series B Preferred Stock.

In September 2024, in connection with the PIPE Financing, the Company issued and sold an aggregate of 2,439 shares of the Company Series A Preferred Stock at a purchase price of $23,000.00 per share.

As of September 30, 2024, convertible preferred stock consisted of the following (in thousands, except share data):

	September 30, 2024			
	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Common Stock Issuable Upon Conversion
Series A Non-Voting Preferred Stock	2,439	2,439	$ 52,841	2,439,000
Series B Non-Voting Preferred Stock	251,504	137,138	$ 2,931	11,428,149

Pursuant to the Certificate of Designation of Preferences, Rights and Limitations of the Series A Non-Voting Convertible Preferred Stock (the "Series A Certificate of Designation") filed in connection with the PIPE Financing, holders of Company Series A Preferred Stock are entitled to receive dividends on shares of Company Series A Preferred Stock equal to, on an as-if-converted-to-Company Common Stock basis, and in the same form as, dividends actually paid on shares of Company Common Stock. Except as provided in the Series A Certificate of Designation or as otherwise required by law, the Company Series A Preferred Stock does not have voting rights. The Company Series A Preferred Stock shall rank on parity with the Company Common Stock and Company Series B Preferred Stock upon any liquidation, dissolution or winding-up of the Company. Subject to the terms and limitations contained in the Series A Certificate of Designation, the Company Series A Preferred Stock issued in the PIPE Financing will not become convertible until the Company's stockholders approve the conversion of the Company Series A Preferred Stock into shares of Company Common Stock in accordance with the listing rules of the Nasdaq Stock Market (the "Stockholder Approval"), which resulted in the Company Series A Preferred Stock being classified outside of stockholders' equity (deficit) on the Company's condensed consolidated balance sheet. Following the Stockholder Approval, each share of Company Series A Preferred Stock will automatically convert into 1,000 shares of Company Common Stock, subject to certain limitations, including that shares of Company Series A Preferred Stock shall not be convertible if the conversion would result in a holder, together with its affiliates, beneficially owning more than 9.99% of the Company's outstanding shares of Company Common Stock as of the applicable conversion date, which may be increased at the holders' option (not to exceed 19.99%), effective in accordance with the terms of the Series A Certificate of Designation. If, at any time after the earlier of Stockholder Approval or six months after the initial issuance of the Series A non-voting preferred stock, the Company fails to deliver to a holder such certificate or certificates, the Company shall, at the request of the holder, pay an amount equal to the closing price of Company's common stock on the trading day immediately prior to the date on which notice to conversion is received by the Company (the "Fair Value") of such undelivered shares, with such payment to be made within two business days from the date of request by the holder, whereupon the Company's obligations to deliver such shares underlying the notice of conversion shall be extinguished upon payment in full of the Fair Value of such undelivered shares; provided, however that such request shall be presumed to have been made by such holder if Stockholder Approval shall not have been obtained prior to the date on which the notice of conversion is delivered to the Company.

Pursuant to the Certificate of Designation of Preferences, Rights and Limitations of the Series B Non-Voting Convertible Preferred Stock (the "Series B Certificate of Designation") filed in connection with the Merger, holders of Company Series B Preferred Stock are entitled to receive dividends on shares of Company Series B Preferred Stock equal to, on an as-if-converted-to-Company Common Stock basis, and in the same form as, dividends actually paid on shares of Company Common Stock. Except as provided in the Series B Certificate of Designation or as otherwise required by law, the Company Series B Preferred Stock does not have voting rights. The Company Series B Preferred Stock shall rank on parity with the Company Common Stock as to the distribution of assets upon any liquidation, dissolution, or winding-up of the Company. Each share of Company Series B Preferred Stock is convertible at the option of the holder, at any time, and without the payment of additional consideration by the holder. As of September 30, 2024, each outstanding share of Company Series B Preferred Stock was convertible into common stock at a ratio of approximately 83.3332:1.

Common Stock

As of September 30, 2024, the Certificate of Incorporation provides for 545,000,000 authorized shares of Company Common Stock. As of September 30, 2024, 34,988,550 shares of Company Common Stock were issued and outstanding, including 2,207,553 shares of RSAs issued and outstanding.

As of September 30, 2024, the Company had common stock reserved for future issuance as follows:

	September 30, 2024
Shares issuable on conversion of Company Series A Preferred Stock	2,439,000
Shares issuable on conversion of Company Series B Preferred Stock	11,428,149
Shares issuable upon exercise of pre-funded warrants	6,202,207
Outstanding and issued stock options	1,287,760
Outstanding and issued employee warrants	3,054,358
Shares available for grant under 2024 Stock Incentive Plan	4,526,324
Shares available for grant under 2024 Employee Stock Purchase Plan	463,489
Total shares of common stock reserved	29,401,287

8. Stock-Based Compensation

2024 Equity Incentive Plan

The 2024 Equity Incentive Plan ("2024 Plan") was adopted by the board of directors of Pre-Merger Oruka on February 6, 2024. The 2024 Plan provided for Pre-Merger Oruka to grant stock options, restricted stock awards, restricted stock units, and other stock-based awards to employees, officers, directors, consultants, and advisors. Equity Incentive Stock options granted under the 2024 Plan generally vest over four years, subject to the participant's continued service, and expire after ten years, although stock options have been granted with vesting terms less than four years. As of

September 30, 2024, there are no shares of common stock available for issuance.

2024 Stock Incentive Plan

On August 22, 2024, the 2024 Stock Incentive Plan ("2024 Stock Plan") was approved by the Company's stockholders and on August 29, 2024, the board of directors of the Company (the "Board") ratified the 2024 Stock Plan. The 2024 Stock Plan allows for the grant of stock options, stock appreciation rights, restricted stock awards, restricted stock units, other stockholder-based awards and incentive bonuses. The 2024 Stock Plan is administered by the Compensation Committee of the Board (the "Compensation Committee") or another committee designated by the Board to administer the Plan. The initial share pool under the 2024 Stock Plan is 4,634,891 shares of Company Common Stock and as of September 30, 2024, there are 4,526,324 shares available in the pool. The shares that may be issued under the 2024 Stock Plan will be automatically increased on January 1 of each year beginning in 2025 and ending with a final increase on January 1, 2034 in an amount equal to 5% of the diluted stock (including Company Common Stock, preferred stock and unexercised pre-funded warrants) on the preceding December 31, unless a lower, or no, increase is determined by the Compensation Committee. Current or prospective employees, officers, non-employee directors, and other independent service providers of the Company and its subsidiaries are eligible to participate in the 2024 Stock Plan.

2024 Employee Stock Purchase Plan

The 2024 Employee Stock Purchase Plan (the "ESPP") was approved by the board of directors of ARCA on July 20, 2024, and by ARCA's stockholders on August 22, 2024. The ESPP became effective on August 29, 2024, at which time 463,489 shares were reserved for issuance. The shares that may be issued under the ESPP will be automatically increased on January 1 of each year beginning in 2025 and ending with a final increase on January 1, 2034 in an amount equal to 1% of the diluted stock (including Company Common Stock, preferred stock and unexercised pre-funded warrants) on the preceding December 31, unless a lower, or no, increase is determined by the Compensation Committee. As of September 30, 2024, no shares have been issued out of the ESPP.

Stock Option Valuation

The following table summarizes the weighted-average assumptions used in calculating the fair value of the awards for the three months ended September 30, 2024 and for the period from February 6, 2024 (inception) to September 30, 2024:

	Three Months Ended September 30, 2024	Period from February 6, 2024 (Inception) to September 30, 2024
Expected term (in years)	6.1	6.1
Expected volatility	97.3%	101.0%
Risk-free interest rate	3.5%	4.3%
Expected dividend yield	—%	—%

Stock Options

The following table summarizes the stock option activities under the 2024 Plan and 2024 Stock Plan for the period of February 6, 2024 (inception) through September 30, 2024:

	Number of Stock Options	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in Thousands)
Balance as of February 6, 2024 (inception)	—	$ —	—	$ —
Granted	1,287,760	$ 7.97		
Exercised	—	$ —		
Forfeited	—	$ —		
Balance as of September 30, 2024	1,287,760	$ 7.97	9.6	$ 21,507
Vested and expected to vest, September 30, 2024	1,287,760	$ 7.97	9.6	$ 21,507
Exercisable, September 30, 2024	—	$ —	—	$ —

The weighted average grant-date fair value per share of stock options granted during the period from February 6, 2024 (inception) to September 30, 2024 was $6.44 per share. Aggregate intrinsic value represents the difference between the estimated fair value of the underlying Company Common Stock and the exercise price of outstanding, in-the-money employee stock options.

Restricted Stock Awards

In February 2024 and March 2024, the Company issued 2,207,553 shares of RSAs to certain employees, directors, and consultants at a price of $0.0001 per share, the then par value of Pre-Merger Oruka Common Stock. Such RSAs have service-based vesting conditions only and vest over a four-year period, during which time all unvested shares are subject to forfeiture in the event the holder's service with the Company voluntarily or involuntarily terminates.

The following table summarizes the RSAs activity for the period from February 6, 2024 (inception) through September 30, 2024:

	Number of RSAs	Weighted Average Grant Date Fair Value
Unvested balance as of February 6, 2024 (inception)	—	$ —
Granted	2,207,553	—
Unvested balance as of September 30, 2024	2,207,553	$ —

Option Agreements and Paruka Warrant Obligation

In March 2024, the Company entered into antibody discovery and option agreements with Paragon and Paruka (the "Option Agreements"). Under the terms of Option Agreements, Paragon identifies, evaluates, and develops antibodies directed against certain mutually agreed therapeutic targets of interest to the Company, and the Company has the exclusive option to, on a research program-by-research program basis, be granted an exclusive, worldwide license to all of Paragon's right, title, and interest in and to the intellectual property resulting from the applicable research program to develop, manufacture and commercialize the antibodies and products directed to the selected target(s). Paruka will be entitled to grants of warrants to purchase a number of shares equal to 1.00% of then outstanding shares of the Company's stock, on a fully diluted basis, on December 31, 2024 and December 31, 2025, at the fair market value determined by the Board (the "Paruka Warrant Obligation"). The grant dates for the issuance of warrants are expected to be December 31, 2024 and December 31, 2025 as all terms of the award, including number of shares and exercise price, will be known by all parties. The service inception period for the grant precedes the grant date, with the full award being vested as of the grant date with no post-grant date service requirement. Accordingly, the warrants expected to be granted to Paruka were accounted for as a liability on the condensed balance sheet and, after the initial recognition, the liability is adjusted to fair value at the end of each reporting period, with changes in fair value recorded in the statement of operations and comprehensive loss as stock-based compensation expenses under research and development expenses. As of September 30, 2024, the estimated fair value of warrants to be granted on December 31, 2024 was $11.0 million. For the three months ended September 30, 2024 and the period from February 6, 2024 (inception) to September 30, 2024, $7.3 million and $7.7 million were recognized as stock-based compensation expenses related to the Paruka Warrant Obligation, respectively.

Employee Warrants

As stated above, on July 3, 2024, the Subscription Agreement was amended and restated, among other things, for employee warrants to be issued to certain Pre-Merger Oruka's employees, directors, and service providers, immediately prior to the closing of the Merger. Pursuant to this amendment, during the three months ended September 30, 2024, the Company issued 3,054,358 employee warrants at an exercise price of $7.80 per warrant, which are accounted as equity in the condensed consolidated financial statements

The following table summarizes the employee warrant activity for the period from February 6, 2024 (inception) through September 30, 2024:

	Number of Warrants	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in Thousands)
Balance as of February 6, 2024 (inception)	—	$ —	—	$ —
Granted	3,054,358	$ 7.80		
Exercised	—	$ —		
Forfeited	—	$ —		
Balance as of September 30, 2024	3,054,358	$ 7.80	9.8	$ 51,038
Vested and expected to vest, September 30, 2024	3,054,358	$ 7.80	9.8	$ 51,038
Vested and exercisable, September 30, 2024	—	$ —	—	$ —

The weighted average grant-date fair value per share of employee warrants granted during the period from February 6, 2024 (inception) to September 30, 2024 was $6.27 per share. Aggregate intrinsic value represents the difference between the estimated fair value of the underlying Company Common Stock and the exercise price of outstanding, in-the-money employee warrants.

The following table summarizes the weighted-average assumptions used in calculating the fair value of the employee warrants for the three months ended September 30, 2024 and for the period from February 6, 2024 (inception) to September 30, 2024:

	Three Months Ended September 30, 2024	Period from February 6, 2024 (Inception) to September 30, 2024
Expected term (in years)	6.1	6.1
Expected volatility	99.0%	99.0%
Risk-free interest rate	4.2%	4.2%
Expected dividend yield	—%	—%

Stock-Based Compensation Expense

The following table summarizes the classification of the Company's stock-based compensation expense in the condensed consolidated statement of operations and comprehensive loss (in thousands):

	Three Months Ended September 30, 2024	Period from February 6, 2024 (Inception) to September 30, 2024
Research and development	$ 7,772	$ 8,310
General and administrative	1,229	1,459
Total	$ 9,001	$ 9,769

As of September 30, 2024, total unrecognized compensation cost related to the unvested stock options was $ 7.5 million, which is expected to be recognized over a weighted average period of approximately 3.4 years. As of September 30, 2024, total unrecognized compensation cost related to the unvested RSAs was less than $0.1 million, which is expected to be recognized over a weighted average period of 3.4 years. As of September 30, 2024, the unrecognized compensation cost related to the employee warrants was $17.8 million, which is expected to be recognized over a weighted average period of 3.6 years.

The following table summarizes the award types of the Company's stock-based compensation expense in the condensed consolidated statement of operations and comprehensive loss (in thousands):

	Three Months Ended September 30, 2024	Period from February 6, 2024 (Inception) to September 30, 2024
Paruka warrant obligation	$ 7,251	$ 7,681
Employee warrants	1,314	1,314
Stock options	427	765
Employee stock purchase plan	9	9
Total	$ 9,001	$ 9,769

9. Income Taxes

No provision for income taxes was recorded for the three months ended September 30, 2024 and for the period of February 6, 2024 (inception) through September 30, 2024. Deferred tax assets generated from the Company's net operating losses have been fully reserved, as the Company believes it is not more likely than not that the benefit will be realized due to the Company's cumulative losses generated to date.

10. Option Agreements

In March 2024, the Company entered into Option Agreements with Paragon and Paruka. Under the terms of the Option Agreements, Paragon identifies, evaluates and develops antibodies directed against certain mutually agreed therapeutic targets of interest to the Company. The Option Agreements include two selected targets, IL-23 ("ORKA-001") and IL-17 A/F ("ORKA-002"). Under the Option Agreements, the Company has the exclusive options to, on a research program-by-research program basis, be granted an exclusive, worldwide license to all of Paragon's right, title and interest in and to the intellectual property resulting from the applicable research program to develop, manufacture and commercialize the antibodies and products directed to the selected targets (each, an "Option"), with the exception of pursuing ORKA-001 for the treatment of inflammatory bowel disease. If the Company exercises its options, it will be required to make non-refundable milestone payments to Paragon of up to $12.0 million under each respective agreement upon the achievement of certain clinical development milestones, up to $10.0 million under each respective agreement upon the achievement of certain regulatory milestones as well as tiered royalty payments in the low-to-mid single-digits beginning on the first commercial sale. From time to time, the Company can choose to add additional targets to the collaboration by mutual agreement with Paragon.

The Company's exclusive Option with respect to each research program for a particular target initiated by the parties ("Research Program") is exercisable at its sole discretion at any time during the period beginning on the initiation of activities under the associated Research Program and ending a specified number of days following (i) with respect to any Research Program other than ORKA-001, the delivery of the data package from Paragon related to the results of the Research Plan activities, or (ii) with respect to ORKA-001, the completion of the IL-23 antibody selection process described in the agreement (the "Option Period"). There is no payment due upon exercise of an Option pursuant to the Option Agreements.

Unless terminated earlier, the Option Agreements shall continue in force on a Research Program-by-Research Program basis until the earlier of: (i) the end of the Option Period for such Research Program, as applicable, if such Option is not exercised by the Company; (ii) the expiration of the 30-day period after the Company exercises its Option with respect to such Research Program, subject to mutually agreed extension, during the Option Period and the parties are unable to finalize and execute a license agreement, and (iii) the expiration of the applicable research term (the "Term"). Upon the expiration of the Term for all then-existing Research Programs, under the Option Agreements, the Option Agreements will automatically expire in its entirety. The Company may terminate the Option Agreements or any Research Program at any time for any or no reason upon 30 days' prior written notice to Paragon, provided that the Company must pay certain unpaid fees due to Paragon upon such termination, as well as any non-cancellable obligations reasonably incurred by Paragon in connection with its activities under any terminated Research Program. Paragon may terminate the Option Agreements or a Research Program immediately upon written notice to the Company if, as a result of any action or failure to act by the Company or its affiliates, such Research Program or all material activities under the applicable Research Plan are suspended, discontinued or otherwise delayed for a certain consecutive number of months. Each party has the right to terminate the Option Agreements or any Research Program upon (i) 30 days' prior written notice of the other party's material breach that remains uncured for the 30-day period and (ii) the other party's bankruptcy.

Pursuant to the Option Agreements, on a research program-by-research program basis following the finalization of the research plan for each respective research program, the Company was required to pay Paragon a one-time, nonrefundable research initiation fee of $0.8 million related to the ORKA-001 program. This amount was recognized as a research and development expense during the period from February 6, 2024 (inception) to

September 30, 2024. In June 2024, pursuant to the Option Agreements with Paragon, the Company completed the selection process of its development candidate for IL-23 antibody for ORKA-001 program. The Company was responsible for 50% of the development costs incurred through the completion of the IL-23 selection process. The Company received the rights to at least one selected IL-23 antibody in June 2024. During the three months ended September 30, 2024, the Company exercised its option for ORKA-001 and recorded a $1.5 million milestone payment related to the achievement of development candidate as research and development expense in the Company's condensed consolidated statements of operations and comprehensive loss for each of the three months ended September 30, 2024 and for the period from February 6, 2024 (inception) to September 30, 2024. The Company's share of development costs incurred during the three months ended September 30, 3024 and for the period from February 6, 2024 (inception) to September 30, 2024 was $0.8 million and $13.2 million, respectively, which were recorded as research and development expenses during the respective periods. An amount of $2.3 million is included in related party accounts payable and other current liabilities as of September 30, 2024.

The Company was also required to reimburse Paragon $ 3.3 million for development costs related to ORKA-002 incurred by Paragon through December 31, 2023 and certain other development costs incurred by Paragon between January 1, 2024 and March 6, 2024 as stipulated by the Option Agreements. This amount was recognized as a research and development expense during the period from February 6, 2024 (inception) to September 30, 2024. The Company is also responsible for the development costs incurred by Paragon from January 1, 2024 through the completion of the IL-17 selection process. The Company recognized an amount of $0.8 million payable to Paragon for the research initiation fee related to ORKA-002 following the finalization of the ORKA-002 research plan. This was recognized as research and development expenses in the period from February 6, 2024 (inception) to September 30, 2024. The Company accounted for development costs of $3.8 million and $6.6 million during the three months ended September 30, 3024 and for the period from February 6, 2024 (inception) to September 30, 2024, respectively, as research and development expenses during the respective periods. An amount of $3.8 million is included in related party accounts payable and other current liabilities as of September 30, 2024.

As part of the Option Agreements, on each of December 31, 2024 and December 31, 2025, the Company will grant warrants to purchase a number of shares equal to 1.00% of outstanding shares as of the date of the grant on a fully diluted basis with an exercise price equal to the fair market value of the underlying shares on the grant date. The warrants are liability-classified and after the initial recognition, the liability is adjusted to fair value at the end of each reporting period, with changes in fair value recorded in the consolidated statement of operations and comprehensive loss (see Note 8) as stock-based compensation expenses under research and development expenses.

The Company expenses the service fees as the associated costs are incurred when the underlying services are rendered. Such amounts are classified within research and development expenses in the accompanying condensed consolidated statement of operations and comprehensive loss.

The Company concluded that the rights obtained under the Option Agreements represent an asset acquisition whereby the underlying assets comprise in-process research and development assets with no alternative future use. The Option Agreements did not qualify as a business combination because substantially all of the fair value of the assets acquired was concentrated in the exclusive license options, which represent a group of similar identifiable assets. The research initiation fee represents a one-time cost on a research program-by-research program basis for accessing research services or resources with benefits that are expected to be consumed in the near term, therefore the amounts paid are expensed as part of research and development costs immediately. Amounts paid as reimbursements of ongoing development cost, monthly development cost fee and additional development expenses incurred by Paragon due to work completed for selected targets prior to the effective date of the Option Agreements that is associated with services being rendered under the related Research Programs are recognized as research and development expense when incurred.

For the three months ended September 30, 2024 and the period from February 6, 2024 (inception) to September 30, 2024, the Company recognized $13.4 million and $33.8 million of expenses, respectively, in connection with services provided by Paragon and Paruka under the Option Agreements.

11. Commitment and Contingencies

Leases

In April 2024, the Company entered into an operating lease agreement for the Company's headquarters in Menlo Park, California, which commenced on June 15, 2024 with an initial term of 39.5 months. The Company leases office space under this noncancelable operating lease agreement. Lease liabilities are based on the net present value of the remaining lease payments over the remaining lease term. In determining the present value of lease payments, the Company used its incremental borrowing rate when measuring operating lease liabilities as discount rates were not implicit or readily determinable.

As of September 30, 2024, the Company had $ 0.9 million of operating lease right-of-use assets, operating lease liability, current of $ 0.1 million, and operating lease liability, noncurrent of $0.8 million on its condensed consolidated balance sheets. As of September 30, 2024, the operating lease arrangement had a remaining lease term of 36.0 months and a discount rate of 17.95%. For the three months ended September 30, 2024 and the period from February 6, 2024 (inception) to September 30, 2024, the Company recorded operating and variable lease expense of $0.1 and $0.2 million, respectively, in general and administrative expenses in its condensed consolidated statements of operations and comprehensive loss.

The following table presents the Company's supplemental cash flow information related to leases (in thousands):

	September 30, 2024
Cash paid for amounts included in the measurement of lease liabilities	
Operating cash flow from operating leases	$ 74

The following table summarizes a maturity analysis of the Company's operating lease liabilities showing the aggregate lease payments as of September 30, 2024 (in thousands):

	Amount
Fiscal year ending December 31,	
2024 (remainder)	$ 63
2025	369
2026	494
2027	380
Total undiscounted lease payments	1,306
Less: imputed interest	(318)
Total discounted lease payments	988
Less: current portion of lease liability	(146)
Non-current portion of lease liability	$ 842

12. Net Loss per Share

Basic and diluted net loss per share attributable to stockholders were calculated as follows (in thousands, except share and per share data):

	Three Months Ended September 30, 2024			Period from February 6, 2024 (Inception) to September 30, 2024		
	Loss Allocation	Weighted Average Shares Outstanding	Loss Per Share – Basic and Diluted	Loss Allocation	Weighted Average Shares Outstanding	Loss Per Share – Basic and Diluted
Common Stock	$ (21,936)	15,013,655	$ (1.46)	$ (47,192)	7,765,381	$ (6.08)
Company Series A Preferred Stock (1)	(697)	477	$ (1,460.62)	(1,121)	184	$ (6,077.13)
Company Series B Preferred Stock (2)	(5,990)	49,191	$ (121.77)	(9,630)	19,015	$ (506.44)
Net loss	$ (28,623)			$ (57,943)		

(1) The weighted-average number of shares of as-converted Company Series A Preferred Stock used in the loss allocation was 477,196 and 184,462 for the three months ended September 30, 2024 and for the period from February 6, 2024 (inception) to September 30, 2024, respectively.

(2) The weighted-average number of shares of as-converted Company Series B Preferred Stock used in the loss allocation was 4,099,227 and 1,584,575 for the three months ended September 30, 2024 and for the period from February 6, 2024 (inception) to September 30, 2024, respectively.

For the computation of basic net loss per share attributable to stockholders, the amount of weighted-average shares outstanding excludes all shares of unvested restricted common stock as such shares are not considered outstanding for accounting purposes until vested. The amount of weighted-average shares outstanding includes the pre-funded warrants as the exercise price is negligible and these warrants are fully vested and exercisable.

The potential shares of common stock that were excluded from the computation of diluted net loss per share attributable to stockholders for the periods presented because including them would have had an anti-dilutive effect were as follows:

	Three Months Ended September 30, 2024	Period from February 6, 2024 (Inception) to September 30, 2024
Outstanding employee warrants to purchase common stock	3,054,358	3,054,358
Outstanding unvested restricted stock awards	2,207,553	2,207,553
Outstanding and issued common stock options	1,287,760	1,287,760
Total	6,549,671	6,549,671

13. Related Party Transactions

Paragon and Paruka each beneficially own less than 5% of the Company's capital stock through their respective holdings of Company Common Stock.

Fairmount beneficially owns more than 5% of the Company's capital, currently has one representative appointed to the Board, and beneficially owns more than 5% of Paragon. Fairmount appointed Paragon's board of directors and has the contractual right to approve the appointment of any executive officers of Paragon.

The following is a summary of related party accounts payable and other current liabilities (in thousands):

	September 30, 2024
Paragon reimbursable Option Agreements' fees	$ 6,140
Paragon reimbursable other research expenses	146
Paragon reimbursable patent expenses	71
	$ 6,357

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

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited consolidated financial statements and the related notes included in Part 1, Item 1 of this Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2024 (this "Quarterly Report"). This discussion contains forward-looking statements that involve risks and uncertainties, such as statements regarding our plans, objectives, expectations, intentions, hopes, beliefs, strategies or projections regarding the future of its pipeline and business and words such as

"may," "will,", "should," "could," "would," "expect," "plan," "anticipate," "believe," "estimate," "project," "potential," "seek," "target," "goal," "intend" and variations of such words and any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, and similar expressions are intended to identify forward-looking statements. You should not place undue reliance on these forward-looking statements. These forward-looking statements are based on current expectations and beliefs concerning future developments and their potential effects. There can be no assurance that future developments affecting us will be those that have been anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our control) or other assumptions that may cause actual results or performance to be materially different from those expressed 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 section of this Quarterly Report entitled "Risk Factors" and elsewhere in this Quarterly Report. These and many other factors could affect our future financial and operating results. We undertake no obligation to update any forward-looking statement to reflect events after the date of this Quarterly Report. As used in this Quarterly Report, unless the context suggests otherwise, "we," "us," "our," "the Company," "Oruka Therapeutics, Inc.," "Oruka," "ARCA biopharma, Inc.," "ARCA," refers to Oruka Therapeutics, Inc. and its consolidated subsidiaries, including Oruka Therapeutics Operating Company LLC, taken as a whole.

Overview

We are a biotechnology company focused on developing novel monoclonal antibody therapeutics for psoriasis ("PsO") and other inflammatory and immunology ("I&I") indications. Our name is derived from *or*, for "skin," and *arukah*, for "restoration" and reflects our mission to deliver therapies for chronic skin diseases that provide patients the greatest possible freedom from their condition. Our strategy is to apply antibody engineering and format innovations to validated modes of action, which we believe will enable us to improve meaningfully upon the efficacy and dosing regimens of standard-of-care medicines while significantly intending to reduce technical and biological risk. Our programs aim to treat and potentially modify disease by targeting mechanisms with proven efficacy and safety involved in disease pathology and the activity of pathogenic tissue-resident memory T cells. Our lead program, ORKA-001, is designed to target the p19 subunit of interleukin-23 ("IL-23p19") for the treatment of PsO. Our co-lead program, ORKA-002, is designed to target interleukin-17A and interleukin-17F ("IL-17A/F") for the treatment of PsO, psoriatic arthritis ("PsA"), and other conditions. These programs each bind their respective targets at high affinity and incorporate half-life extension technology with the aim to increase exposure and decrease dosing frequency. We believe that our focused strategy, differentiated portfolio, and deep expertise position us to set a new treatment standard in large I&I markets with continued unmet need.

Since our inception in February 2024, we have devoted substantially all of our resources to raising capital, organizing and staffing the company, business and scientific planning, conducting discovery and research activities, establishing arrangements with third parties for the manufacture of our programs and component materials, and providing general and administrative support for these operations. We do not have any programs approved for sale and have not generated any revenue from product sales. To date, we have funded our operations primarily with proceeds from the issuance of convertible preferred stock, common stock, convertible note, pre-funded warrants, and the proceeds from the reverse recapitalization and merger with ARCA biopharma, Inc., our Pre-Closing Financing and subsequent PIPE Financing (as defined and further described in "*Recent developments"* below).

Since our inception, we have incurred significant losses and negative cash flows from our operations. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of any programs we may develop. We generated net losses of $28.6 million for the three months ended September 30, 2024 and $57.9 million for the period from February 6, 2024 (inception) to September 30, 2024. For the period from February 6 (inception) to September 30, 2024, we have used net cash of $39.0 million for our operating activities.

We had cash and cash equivalents of $410.9 million as of September 30, 2024. We expect that our existing cash and cash equivalents will be sufficient to fund our operating plans for at least twelve months from the date of filing of this Quarterly Report. We expect to continue to incur substantial losses for the foreseeable future, and our transition to profitability will depend upon successful development, approval and commercialization of our product candidates and upon achievement of sufficient revenues to support our cost structure.

ORKA-001

ORKA-001 is a high affinity, extended half-life monoclonal antibody ("mAb") designed to target IL-23p19. IL-23 is a pro-inflammatory cytokine that plays a critical role in the proliferation and development of T helper 17 ("Th17") cells, which are the primary drivers of several autoimmune and inflammatory disorders, including PsO. IL-23 is composed of two subunits: a p40 subunit that is shared with IL-12 and a p19 subunit that is specific to IL-23. First-generation IL-23 antibodies bound p40 and inhibited both IL-12 and IL-23 signaling, while more recent IL-23 antibodies targeting the p19 subunit have shown improved efficacy and safety. Based on preclinical evidence, we believe that ORKA-001 could achieve higher response rates than established therapies in PsO while requiring less frequent dosing and maintaining the favorable safety profile of therapies targeting IL-23p19.

ORKA-001 is engineered with YTE half-life extension technology, a specific three amino acid change in the Fc domain to modify the pH-dependent binding to the neonatal Fc receptor. As a result, it has a pharmacokinetic profile that has the potential to support a SQ injection as infrequently as once or twice a year. In addition, emerging evidence suggests that IL-23 blockade can modify the disease biology of PsO, possibly leading to durable remissions and preventing the development of PsA. We believe that the expected characteristics of ORKA-001 increase its potential to deliver these disease-modifying benefits.

We plan to initiate a Phase 1 trial of ORKA-001 in the first quarter of 2025. We expect to share interim data from the first-in-human trial in healthy volunteers, including initial pharmacokinetic data, in the second half of 2025 and initial efficacy data in PsO patients in the second half of 2026.

ORKA-002

ORKA-002 is a high affinity, extended half-life mAb designed to target IL-17A and IL-17F ("IL-17A/F"). IL-17 inhibition has become central to the treatment of psoriatic diseases, including PsO and PsA, and has also shown efficacy in other I&I indications, such as hidradenitis suppurativa and axial spondyloarthritis. More recently, the importance of inhibiting the IL-17F isoform along with IL-17A has become appreciated, and dual blockade with the recently approved therapy Bimzelx® (bimekizumab) has led to higher response rates in patients than blockade of IL-17A alone. ORKA-002 is designed to bind IL-17A/F at similar epitopes, or binding sites, and affinity ranges as bimekizumab, but incorporates half-life extension technology that could enable more convenient dosing intervals. We plan to initiate a Phase 1 trial of ORKA-002 in the third quarter of 2025. We expect to share interim data from the first-in-human trial in healthy volunteers, including initial pharmacokinetic data, in the first half of 2026.

We view ORKA-002 and ORKA-001 as highly complementary. Patients with moderate-to-severe PsO that have purely skin manifestations are most often treated with IL-23 inhibitors due to the high efficacy and tolerability of this mechanism. However, for patients who also have joint involvement, or signs and symptoms of PsA, an IL-17 inhibitor is typically used due to its efficacy in addressing both skin and joint symptoms. In addition, IL-17 inhibitors are often used in patients with highly resistant skin symptoms that do not adequately resolve through treatment with an IL-23 inhibitor. Together, ORKA-001 and ORKA-002 provide the potential to offer a highly compelling product profile for most patients with PsO and/or PsA, as well as the opportunity to address additional I&I indications.

Additional Pipeline Program

We have a third mAb program, ORKA-003, designed to target an undisclosed pathway. Our strategy as a company is to remain highly focused on I&I diseases, and specifically on inflammatory dermatology conditions. Our third program provides the potential for indication expansion beyond PsO and may create combination opportunities with our more advanced programs.

Recent Developments

The Merger

On August 29, 2024, we consummated the previously announced business combination ("Closing") pursuant to that certain Agreement and Plan of Merger and Reorganization, dated April 3, 2024 (the "Merger Agreement"), by and among ARCA, Atlas Merger Sub Corp, a wholly owned subsidiary of ARCA ("First Merger Sub"), Atlas Merger Sub II, LLC, a wholly owned subsidiary of ARCA ("Second Merger Sub") and Oruka Therapeutics, Inc. ("Pre-Merger Oruka"), pursuant to which, among other matters, Pre-Merger Oruka merged with and into First Merger Sub, with Pre-Merger Oruka continuing as a wholly owned subsidiary of ARCA and the surviving corporation of the merger ("First Merger") and following that, Pre-Merger Oruka then merged with and into Second Merger Sub, with Second Merger Sub being the surviving entity of the second merger (the "Second Merger" and together with the First Merger, the "Merger"). Following consummation of the Merger, we effected a 1-for-12 reverse stock split (the "Reverse Stock Split") of the common stock, par value $0.001 per share, of the Company ("Company Common Stock"), which became effective on September 3, 2024. The Company Common Stock commenced trading on a post-Reverse Stock Split, post-Merger basis at the opening of trading on September 3, 2024. Second Merger Sub changed its corporate name to "Oruka Therapeutics Operating Company, LLC" and ARCA changed its name to "Oruka Therapeutics, Inc." We are led by the pre-reverse capitalization Pre-Merger Oruka management team and remains focused on developing biologics to optimize the treatment of inflammatory skin diseases.

Pre-Closing Financing

Immediately prior to the execution and delivery of the Merger Agreement on April 3, 2024, certain new and existing investors of Pre-Merger Oruka entered into a subscription agreement with Pre-Merger Oruka (the "Subscription Agreement"), pursuant to which, and on the terms and subject to the conditions of which, immediately prior to the Closing, those investors purchased shares of common stock of Pre-Merger Oruka ("Pre-Merger Oruka Common Stock") and Pre-Merger Oruka pre-funded warrants for gross proceeds of approximately $275.0 million (which includes $25.0 million of proceeds previously received from the issuance of the Convertible Note (refer to Note 6 in our condensed consolidated financial statements included in Part I- Item 1 of this Quarterly Report for additional details) and accrued interest on such note which converted to shares of Pre-Merger Oruka Common Stock) (the "Pre-Closing Financing"). We incurred transaction costs of $20.5 million which was recorded as a reduction to additional paid-in capital in the unaudited condensed consolidated financial statements. At the Closing, the shares of Pre-Merger Oruka Common Stock and Pre-Merger Oruka pre-funded warrants issued pursuant to the Subscription Agreement were converted into shares of Company Common Stock and pre-funded warrants of Company Common Stock in accordance with the Exchange Ratio (defined below).

In accordance with an Exchange Ratio determined by terms of the Merger Agreement and upon the effective time of the First Merger (the "First Effective Time"), (i) each then-issued and outstanding share of Pre-Merger Oruka Common Stock including outstanding and unvested Pre-Merger Oruka restricted stock and shares of Pre-Merger Oruka Common Stock issued in connection with the Subscription Agreement, were converted into the right to receive a number of shares of Company Common Stock, equal to the exchange ratio of 6.8569 shares of Company Common Stock (the "Exchange Ratio"), which were subject to the same vesting provisions as those immediately prior to the Merger, (ii) each share of Pre-Merger Oruka Series A convertible preferred stock, par value $0.0001 ("Pre-Merger Oruka Series A Preferred Stock"), outstanding immediately prior to the First Effective Time was converted into the right to receive a number of shares of ARCA Series B non-voting convertible preferred stock, par value $0.001 per share, which are convertible into shares of Company Common Stock at a conversion ratio of approximately 83.3332:1, (iii) each outstanding option to purchase Pre-Merger Oruka Common Stock was converted into an option to purchase shares of Company Common Stock, (iv) each outstanding warrant to purchase shares of Pre-Merger Oruka Common Stock was converted into a warrant to purchase shares of Company Common Stock, and (v) each share of Company Common Stock issued and outstanding at the First Effective Time remain issued and outstanding in accordance with its terms and such shares Subsequent to the close of the merger, the common stock shares were then, subject to the reverse stock split of 1-for-12 effected on September 3, 2024.

As part of the Pre-Closing Financing and the Closing, the investors in the Pre-Closing Financing received 22,784,139 shares of Company Common Stock in exchange for 39,873,706 shares of Pre-Merger Oruka Common Stock (which includes the issuance of 2,722,207 shares of Company Common Stock in exchange for 4,764,032 shares of Pre-Merger Oruka Common Stock on the conversion of Convertible Note along with the accrued interest through the conversion date) and 5,522,207 Company pre-funded warrants in exchange for 9,664,208 Pre-Merger pre-funded warrants.

The Merger was accounted for as a reverse recapitalization in accordance with U.S. GAAP. Under this method of accounting, Pre-Merger Oruka was deemed to be the accounting acquirer for financial reporting purposes. This determination was primarily based on the fact that, immediately following the Merger: (i) Pre-Merger Oruka stockholders own a substantial majority of the voting rights in the combined company; (ii) Pre-Merger Oruka's largest stockholders retain the largest interest in the combined company; (iii) Pre-Merger Oruka designated a majority of the initial members of the board of directors of the combined company; and (iv) Pre-Merger Oruka's executive management team became the management team of the combined company. Accordingly, for accounting purposes: (i) the Merger was treated as the equivalent of Pre-Merger Oruka issuing stock to acquire the net assets of ARCA; and (ii) the reported historical operating results of the combined company prior to the Merger are those of Pre-Merger Oruka. Additional information regarding the Merger is included in Note 3 to the condensed consolidated financial statements included in Part I – Item 1 of this Quarterly Report.

Reverse Stock Split

On September 3, 2024, we effected the Reverse Stock Split, a 1-for-12 reverse stock split of Company Common Stock. The par value per share and the number of authorized shares were not adjusted as a result of the Reverse Stock Split. The shares of Company Common Stock underlying outstanding stock options, common stock warrants and other equity instruments were proportionately reduced and the respective exercise prices, if applicable, were proportionately increased in accordance with the terms of the agreements governing such securities. All references to common stock, options to purchase common stock, outstanding common stock warrants, common stock share data, per share data, and related information contained in the condensed consolidated financial statements have been retrospectively adjusted to reflect the effect of the Reverse Stock Split for all periods presented, unless otherwise specifically indicated or the context otherwise requires.

PIPE Financing

On September 11, 2024, we entered into a Securities Purchase Agreement for a private placement (the "PIPE Financing") with certain institutional

and accredited investors. The closing of the PIPE Financing occurred on September 13, 2024.

Pursuant to the Securities Purchase Agreement, the investors purchased an aggregate of 5,600,000 shares of Company Common Stock at a purchase price of $23.00 per share, an aggregate of 2,439 shares of the Company's Series A non-voting convertible preferred stock, par value $0.001 per share ("Company Series A Preferred Stock"), at a purchase price of $23,000.00 per share (each Company Series A Preferred Stock is convertible into 1,000 shares of Company Common Stock), and pre-funded warrants to purchase an aggregate of 680,000 shares of Company Common Stock at a purchase price of $22.999 per pre-funded warrant, for aggregate net proceeds of approximately $188.7 million (net of issuance costs of $11.8 million).

Components of Results of Operations

Revenue

To date, we have not generated revenue from any sources, including product sales, and do not expect to generate any revenue from the sale of products in the foreseeable future. If our development efforts for our product candidates are successful and result in regulatory approval, we may generate revenue in the future from product sales or payments from future collaboration or license agreements that we may enter into with third parties, or any combination thereof. We cannot predict if, when, or to what extent we will generate revenue from the commercialization and sale of our product candidates. We may never succeed in obtaining regulatory approval for any of our product candidates.

Operating Expenses

Research and Development

Research and development expenses consist primarily of costs incurred in connection with the development and research of our programs. These expenses include costs of funding research performed by third parties, including Paragon Therapeutics, Inc. ("Paragon"), that conduct research and development activities on our behalf, expenses incurred in connection with continuing our current research programs and discovery-phase development of any programs we may identify, including under future agreements with third parties, such as consultants and contractors, personnel-related expenses, including salaries, bonuses, employee benefits, stock-based compensation expense, and allocated human resource costs, information technology costs, and facility-related costs, including rent, maintenance, utilities, and depreciation for our leased office space.

We expense research and development costs as incurred. Our primary focus since inception has been the identification and development of our pipeline programs. Our research and development expenses primarily consist of external costs, such as fees paid to Paragon under the Option Agreements. We separately track the amount of costs incurred under the Option Agreements with Paragon between ORKA-001 and ORKA-002. See "— *Contractual Obligations and Commitments*" below for further details on the Option Agreements.

We expect our research and development expenses to increase substantially for the foreseeable future as we advance our product candidates into and through preclinical studies and clinical trials, pursue regulatory approval of our product candidates and expand our pipeline of product candidates.

General and Administrative

General and administrative expenses consist primarily of personnel-related expenses, including salaries, bonuses, employee benefits, and stock-based compensation, for our executive and other administrative personnel. Other significant general and administrative expenses include legal services, including intellectual property and corporate matters; professional fees for accounting, auditing, tax, insurance, and allocated human resource costs, information technology costs, and facility-related costs, including rent, utilities, maintenance, and depreciation for our leased office space.

We expect our general and administrative expenses will increase substantially for the foreseeable future as we anticipate an increase in our personnel headcount to support the expansion of research and development activities, as well as to support our operations generally. We also expect to continue to incur significant expenses associated with being a public company, including costs related to accounting, audit, legal, regulatory, and tax-related services associated with maintaining compliance with applicable Nasdaq and SEC requirements; additional director and officer insurance costs; and investor and public relations costs. We also expect to incur additional intellectual property-related expenses as we file patent applications to protect innovations arising from our research and development activities.

Other Income (Expense), Net

Other income (expense), net includes interest expense on the convertible note from a related party, interest income, and foreign currency transactions gains and losses. Interest expense relates to a convertible note (the "Convertible Note") issued to Fairmount Healthcare Fund II, L.P. ("Fairmount") in March 2024.

Income Taxes

No provision for income taxes was recorded for the three months ended September 30, 2024 and for the period from February 6, 2024 (inception) through September 30, 2024. Deferred tax assets generated from our net operating losses have been fully reserved as we believe it is not more likely than not that the benefit will be realized due to its cumulative losses generated to date.

Results of Operations for the Three Months Ended September 30, 2024

The following table summarizes our results of operations and comprehensive loss for the period presented (in thousands):

	Three Months Ended September 30, 2024
Operating expenses	
Research and development[(1)]	$ 25,691
General and administrative[(2)]	3,758
Total operating expenses	29,449
Loss from operations	(29,449)
Other income (expense)	
Interest income	1,330
Interest expense[(3)]	(504)

Total other income, net	826
Net loss and comprehensive loss	$ (28,623)

(1) Includes related party amount of $13,537 for the three months ended September 30, 2024

(2) Includes related party amount of $71 for the three months ended September 30, 2024

(3) Includes related party amount of $504 for the three months ended September 30, 2024

Research and Development Expenses

The following table summarizes our research and development expenses for the period presented (in thousands):

	Three Months Ended September 30, 2024
External research and development costs by selected target:	
ORKA-001[(1)]	$ 11,761
ORKA-002[(2)]	4,147
Other research and development costs:	
Personnel-related (including stock-based compensation) [(3)]	9,076
Other[(4)]	707
Total research and development expenses	$ 25,691

(1) Includes related party amount of $2,316 for the three months ended September 30, 2024

(2) Includes related party amount of $3,824 for the three months ended September 30, 2024

(3) Includes related party amount of $7,251 for the three months ended September 30, 2024

(4) Includes related party amount of $146 for the three months ended September 30, 2024

Research and development expenses were $25.7 million for the three months ended September 30, 2024 and consisted primarily of the following:

- $2.3 million of research and development expense due to Paragon for services rendered under the Option Agreements for ORKA-001, including $1.5 million of milestone payment due to Paragon upon exercise of option to enter into a license agreement and achievement of development candidate for IL-23;
- $9.4 million of research and development expenses on chemistry, manufacturing, and development costs for ORKA-001, including $3.2 million of toxicology testing for ORKA-001 with a third-party contract research organization;
- $3.8 million of research and development expense due to Paragon for services rendered under the Option Agreements for ORKA-002;
- $9.1 million of personnel-related costs related to salaries, benefits and other compensation-related costs, and stock-based compensation expense of $7.8 million, including $7.3 million for stock-based compensation related to Paruka Holding LLC (“Paruka”) warrants; and
- $0.7 million of other research expenses and allocated human resource costs, information technology costs, and facility-related costs, including rent, maintenance, utilities, and depreciation for our leased office space.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the period presented (in thousands):

	Three Months Ended September 30, 2024
Personnel-related (including stock-based compensation)	$ 2,435
Professional and consulting fees	701
Legal fees related to patent [(1)]	116
Other	506
Total general and administrative expenses	$ 3,758

(1) Includes related party amount of $71 for the three months ended September 30, 2024

General and administrative expenses were $3.8 million for the three months ended September 30, 2024 and consisted primarily of the following:

- $2.4 million of personnel-related costs related to salaries, benefits and other compensation-related costs, including stock-based compensation of $1.2 million;
- $0.7 million of professional and consulting fees associated with accounting, audit, and legal fees to support our business activity and operations of a public company;
- $0.1 million of legal fees due to Paragon associated with patent related activities; and
- $0.5 million of other business expense and allocated human resource costs, information technology costs, and facility-related costs, including rent, maintenance, utilities, and depreciation for our leased office space.

Total Other Income (Expense), Net

Interest income from money market funds was $1.3 million for the three months ended September 30, 2024.

Interest expense was $0.5 million for the three months ended September 30, 2024 relating to the Convertible Note from Fairmount.

Results of Operations for the Period of February 6, 2024 (Inception) to September 30, 2024

The following table summarizes our results of operations and comprehensive loss for the period presented (in thousands):

	Period from February 6, 2024 (Inception) to September 30, 2024
Operating expenses	
Research and development[(1)]	$ 49,557
General and administrative[(2)]	8,248
Total operating expenses	57,805
Loss from operations	(57,805)
Other income (expense)	
Interest income	1,330
Interest expense[(3)]	(1,468)
Total other expense, net	(138)
Net loss and comprehensive loss	$ (57,943)

(1) Includes related party amount of $33,967 for the period from February 6, 2024 (inception) to September 30, 2024

(2) Includes related party amount of $1,339 for the period from February 6, 2024 (inception) to September 30, 2024

(3) Includes related party amount of $1,468 for the period from February 6, 2024 (inception) to September 30, 2024

Research and Development Expenses

The following table summarizes our research and development expenses for the period presented (in thousands):

	Period from February 6, 2024 (Inception) to September 30, 2024
External research and development costs by selected target:	
ORKA-001[(1)]	$ 26,939
ORKA-002[(2)]	10,987
Other research and development costs:	
Personnel-related (including stock-based compensation)[(3)]	10,684
Other[(4)]	947
Total research and development expenses	$ 49,557

(1) Includes related party amount of $15,478 for the period from February 6, 2024 (inception) to September 30, 2024

(2) Includes related party amount of $10,662 for the period from February 6, 2024 (inception) to September 30, 2024

(3) Includes related party amount of $7,681 for the period from February 6, 2024 (inception) to September 30, 2024

(4) Includes related party amount of $146 for the period from February 6, 2024 (inception) to September 30, 2024

Research and development expenses were $49.6 million for the period from February 6, 2024 (inception) to September 30, 2024 and consisted primarily of the following:

- $15.5 million of research and development expense due to Paragon for services rendered under the Option Agreements for ORKA-001, including $1.5 million of milestone payment due to Paragon upon exercise of option to enter into a license agreement and achievement of development candidate for IL-23, and $5.9 million of research and development expense due to Paragon incurred through March 31, 2024 upon completion of IL-23 selection process;
- $11.4 million of research and development expense on chemistry, manufacturing, and development costs for ORKA-001, including $3.4 million in toxicology testing for ORKA-001 with a third-party contract research organization;
- $11.0 million of research and development expense primarily due to Paragon for services rendered under the Option Agreements for ORKA-002;

- $10.7 million of personnel-related costs related to salaries, benefits, and other compensation-related costs, and stock-based compensation expense of $8.3 million, including $7.7 million for stock-based compensation related to Paruka warrants; and
- $0.9 million of other research expense and allocated human resource costs, information technology costs, and facility-related costs, including rent, maintenance, utilities, and depreciation for our leased office space.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the period presented (in thousands):

	Period from February 6, 2024 (Inception) to September 30, 2024
Personnel-related (including stock-based compensation)[(1)]	$ 4,590
Professional and consulting fees	2,330
Legal fees related to patent [(2)]	606
Other[(3)]	722
Total general and administrative expenses	$ 8,248

(1) Includes related party amount of $609 for the period from February 6, 2024 (inception) to September 30, 2024

(2) Includes related party amount of $550 for the period from February 6, 2024 (inception) to September 30, 2024

(3) Includes related party amount of $180 for the period from February 6, 2024 (inception) to September 30, 2024

General and administrative expenses were $8.2 million for the period from February 6, 2024 (inception) to September 30, 2024 and consisted primarily of the following:

- $4.6 million of personnel-related costs related to recruiting costs, salaries, benefits and other compensation-related costs, including stock-based compensation of $1.5 million and $0.6 million of personnel-related costs are amounts due to Paragon related to recruiting costs for hiring our executive team, legal, and finance and accounting functions;
- $2.3 million of professional and consulting fees associated with accounting, audit, and legal fees associated with becoming a public company;
- $0.6 million of legal fees due to Paragon associated with patent related activities; and
- $0.7 million of other business expenses and allocated human resource costs, information technology costs, and facility-related costs, including rent, maintenance, utilities, and depreciation for our leased office space, including $0.2 million of other business expenses due to Paragon.

Total Other Income (Expense), Net

Interest income from money market funds was $1.3 million for the period from February 6, 2024 (inception) to September 30, 2024.

Interest expense was $1.5 million for the period from February 6, 2024 (inception) to September 30, 2024 relating to the Convertible Note from Fairmount.

Liquidity and Capital Resources

As of September 30, 2024, we had $410.9 million of cash and cash equivalents.

Since our inception, we have incurred significant operating losses and negative cash flow from operations. We expect to incur significant expenses and operating losses for the foreseeable future as we continue the pre-clinical and clinical development of our programs and continue our early-stage research activities. We have not yet commercialized any products and we do not expect to generate revenue from sales of products for several years, if at all. As of September 30, 2024, we had funded our operations primarily with proceeds from issuances of convertible preferred stock, common stock, convertible note, and pre-funded warrants. In March 2024, we received $3.0 million in gross proceeds from the issuance of Pre-Merger Oruka Series A Preferred Stock and $25.0 million in gross proceeds from the issuance of the Convertible Note, both of which were related party transactions. In August 2024, we raised approximately $228.0 million in net proceeds from Pre-Closing Financing and received $4.9 million in cash from ARCA upon consummation of the Merger. In September 2024, we received approximately $188.7 million in net proceeds from the issuance of common stock, Company Series A Preferred Stock, and pre-funded warrants in connection with the PIPE Financing.

Our primary use of cash is to fund the development of our product candidates, and advance our pipeline. This includes both the research and development costs and the general and administrative expenses required to support those operations. Since we are a clinical stage biotechnology company, we have incurred significant operating losses since our inception and we anticipate such losses, in absolute dollar terms, to increase as we continue to pursue clinical development of our product candidates, prepare for the potential commercialization of our product candidates, and expand our development efforts in our pipeline of nonclinical candidates. We expect that our existing cash and cash equivalents will be sufficient to fund our operating plans for at least twelve months from the date of filing of this Quarterly Report. We will need to secure additional financing in the future to fund additional research and development, and before a commercial drug can be produced, marketed and sold. If we are unable to obtain additional financing or generate license or product revenue, the lack of liquidity could have a material adverse effect on our company.

Cash Flows

The following table summarizes our cash flows for the period presented (in thousands):

	Period from February 6, 2024 (Inception) to September 30, 2024
Net cash used in operating activities	$ (39,019)
Net cash used in investing activities	(171)
Net cash provided by financing activities	450,065
Net increase in cash and cash equivalents	$ 410,875

Operating Activities

From February 6, 2024 (inception) to September 30, 2024, net cash used in operating activities was $39.0 million, which was primarily attributable to a net loss of $57.9 million, offset by non-cash charges of $11.3 million and net cash provided by changes in operating activities of $7.6 million. Non-cash charges primarily consisted of a $9.8 million increase in stock-based compensation expense (primarily from Paruka Warrant Obligation) and $1.5 million of non-cash interest expense. Net cash provided by changes in our operating activities primarily consisted of a $1.6 million increase in accounts payable, $1.7 million increase in accrued expenses and other current liabilities, $6.4 million increase in related parties accounts payable and other current liabilities, partially offset by a $2.0 million increase in prepaid expenses and other current assets. The increase in amounts due to related parties, accounts payable, and accrued expenses and other current liabilities was primarily due to an increase in our business activity, as well as vendor invoicing and payments. The increase in prepaid expenses and other current assets was primarily due to prepaid research and development expenses with our contract research organization.

Investing Activities

From February 6, 2024 (inception) to September 30, 2024, net cash used in investing activities was $0.2 million, which was attributable to purchases of property and equipment.

Financing Activities

From February 6, 2024 (inception) to September 30, 2024, net cash provided by financing activities was $450.1 million, consisting of $2.9 million of net proceeds from the issuance of Series B Preferred Stock, $25.0 million of net proceeds from the issuance of the Convertible Note, $228.1 million of net proceeds from the Pre-Closing Financing, $189.1 million of net proceeds from the PIPE Financing, and $4.9 million of cash acquired in connection with the reverse recapitalization.

Contractual Obligations and Commitments

We enter into contracts in the normal course of business with contract research organizations (“CROs”) for clinical trials, with contract manufacturing organizations (“CMOs”) for clinical supplies manufacturing and with other vendors for preclinical studies, supplies and other services and products for operating purposes. These contracts generally provide for termination on notice or may have a potential termination fee if a purchase order is cancelled within a specified time, and therefore are cancelable contracts. We do not expect any such contract terminations and did not have any non-cancellable obligations under these agreements as of September 30, 2024.

Option Agreements

In March 2024, we entered into antibody discovery and option agreements with Paragon and Paruka (the “Option Agreements”). Under the terms of the Option Agreements, Paragon identifies, evaluates and develops antibodies directed against certain mutually agreed therapeutic targets of interest to us. The Option Agreements include two selected targets, IL-23 (“ORKA-001”) and IL-17 A/F (“ORKA-002”). Under the Option Agreements, we have the exclusive options to, on a research program-by-research program basis, be granted an exclusive, worldwide license to all of Paragon’s right, title and interest in and to the intellectual property resulting from the applicable research program to develop, manufacture and commercialize the antibodies and products directed to the selected targets (each, an “Option”), with the exception of pursuing ORKA-001 for the treatment of inflammatory bowel disease. If we exercise our options, we will be required to make non-refundable milestone payments to Paragon of up to $12.0 million under each respective agreement upon the achievement of certain clinical development milestones, up to $10.0 million under each respective agreement upon the achievement of certain regulatory milestones as well as tiered royalty payments in the low-to-mid single-digits beginning on the first commercial sale. From time to time, we can choose to add additional targets to the collaboration by mutual agreement with Paragon. During the three months ended September 30, 2024, we exercised our option for ORKA-001 and recorded a $1.5 million milestone payment related to the achievement of development candidate as research and development expense in our condensed consolidated statements of operations and comprehensive loss for the three months ended September 30, 2024. As of September 30, 2024, this amount is included under related party accounts payable and other current liabilities on the condensed consolidated balance sheet.

Our exclusive Option with respect to each research program for a particular target initiated by the parties (“Research Program”) is exercisable at our sole discretion at any time during the period beginning on the initiation of activities under the associated Research Program and ending a specified number of days following (i) with respect to any Research Program other than ORKA-001, the delivery of the data package from Paragon related to the results of the Research Plan activities, or (ii) with respect to ORKA-001, the completion of the IL-23 antibody selection process described in the agreement (the “Option Period”). There is no payment due upon exercise of an Option pursuant to the Option Agreements.

Unless terminated earlier, the Option Agreements shall continue in force on a Research Program-by-Research Program basis until the earlier of: (i) the end of the Option Period for such Research Program, as applicable, if such Option is not exercised by us; (ii) the expiration of the 30-day period after we exercise our Option with respect to such Research Program, subject to mutually agreed extension, during the Option Period and the parties are unable to finalize and execute a license agreement, and (iii) the expiration of the applicable research term (the “Term”). Upon the expiration of the Term for all then-existing Research Programs, under the Option Agreements, the Option Agreements will automatically expire in its entirety. We may terminate the Option Agreements or any Research Program at any time for any or no reason upon 30 days’ prior written notice to Paragon, provided that we must pay certain unpaid fees due to Paragon upon such termination, as well as any non-cancellable obligations reasonably incurred by Paragon in connection with its activities under any terminated Research Program. Paragon may terminate the Option Agreements or a Research Program immediately upon written notice to us if, as a result of any action or failure to act by us or our affiliates, such Research Program or all material activities under the applicable Research Plan are suspended, discontinued or otherwise delayed for a certain consecutive number of months. Each party has the right to terminate the Option Agreements or any Research Program upon (i) 30 days’ prior written notice of the other party’s material breach that remains uncured for the 30-day period and (ii) the other party’s bankruptcy.

Pursuant to the Option Agreements, on a research program-by-research program basis following the finalization of the research plan for each

respective research program, we were required to pay Paragon a one-time, nonrefundable research initiation fee of $0.8 million related to the ORKA-001 program. This amount was recognized as a research and development expense during the period from February 6, 2024 (inception) to September 30, 2024. In June 2024, pursuant to the Option Agreements with Paragon, we completed the selection process of our development candidate for IL-23 antibody for ORKA-001 program. We were responsible for 50% of the development costs incurred through the completion of the IL-23 selection process. We received the rights to at least one selected IL-23 antibody in June 2024. During the three months ended September 30, 2024, we exercised our option for ORKA-001 and recorded a $1.5 million milestone payment related to the achievement of development candidate as research and development expense in our condensed consolidated statements of operations and comprehensive loss for each of the three months ended September 30, 2024 and for the period from February 6, 2024 (inception) to September 30, 2024. Our share of development costs incurred during the three months ended September 30, 3024 and for the period from February 6, 2024 (inception) to September 30, 2024 was $0.8 million and $13.2 million, respectively, which were recorded as research and development expenses during the respective periods. An amount of $2.3 million is included in related party accounts payable and other current liabilities as of September 30, 2024.

We were also required to reimburse Paragon $3.3 million for development costs related to ORKA-002 incurred by Paragon through December 31, 2023 and certain other development costs incurred by Paragon between January 1, 2024 and March 6, 2024 as stipulated by the Option Agreements. This amount was recognized as a research and development expense during the period from February 6, 2024 (inception) to September 30, 2024. We are also responsible for the development costs incurred by Paragon from January 1, 2024 through the completion of the IL-17 selection process. We recognized an amount of $0.8 million payable to Paragon for the research initiation fee related to ORKA-002 following the finalization of the ORKA-002 research plan. This was recognized as research and development expenses in the period from February 6, 2024 (inception) to September 30, 2024. We accounted for development costs of $3.8 million and $6.6 million during the three months ended September 30, 3024 and for the period from February 6, 2024 (inception) to September 30, 2024, respectively, as research and development expenses during the respective periods. An amount of $3.8 million is included in related party accounts payable and other current liabilities as of September 30, 2024.

As part of the Option Agreements, on each of December 31, 2024 and December 31, 2025, we will grant warrants to purchase a number of shares equal to 1.00% of outstanding shares as of the date of the grant on a fully diluted basis with an exercise price equal to the fair market value of the underlying shares on the grant date. The warrants are liability-classified and after the initial recognition, the liability is adjusted to fair value at the end of each reporting period, with changes in fair value recorded in the consolidated statement of operations and comprehensive loss as stock-based compensation expenses under research and development expenses.

We expense the service fees as the associated costs are incurred when the underlying services are rendered. Such amounts are classified within research and development expenses in the accompanying condensed consolidated statement of operations and comprehensive loss.

We concluded that the rights obtained under the Option Agreements represent an asset acquisition whereby the underlying assets comprise in-process research and development assets with no alternative future use. The Option Agreements did not qualify as a business combination because substantially all of the fair value of the assets acquired was concentrated in the exclusive license options, which represent a group of similar identifiable assets. The research initiation fee represents a one-time cost on a research program-by-research program basis for accessing research services or resources with benefits that are expected to be consumed in the near term, therefore the amounts paid are expensed as part of research and development costs immediately. Amounts paid as reimbursements of on-going development cost, monthly development cost fee and additional development expenses incurred by Paragon due to work completed for selected targets prior to the effective date of the Option Agreements that is associated with services being rendered under the related Research Programs are recognized as research and development expense when incurred.

For the three months ended September 30, 2024 and the period from February 6, 2024 (inception) to September 30, 2024, we recognized $13.4 million and $33.8 million of expenses, respectively, in connection with services provided by Paragon and Paruka under the Option Agreements.

Note Payable with Related Party

In March 2024, we entered into a Series A Preferred Stock and Convertible Note Purchase Agreement (the “Purchase Agreement”) with Fairmount, whereby we issued the Convertible Note, with an initial principal amount of $25.0 million that, at the time of issuance, could be converted into Pre-Merger Oruka Series A Preferred Stock (or a series of preferred shares that is identical in respect to the shares of preferred shares issued in its next equity financing) or shares of Pre-Merger Oruka Common Stock in exchange for aggregate proceeds of $25.0 million. The Convertible Note accrued interest at a rate of 12.0% per annum. At issuance, the Convertible Note required all unpaid interest and principal to mature on December 31, 2025 (the “Maturity Date”) and prepayment was not permitted without prior written consent of Fairmount. At issuance, the principal payment along with the accrued interest on the Convertible Note was due in full on the Maturity Date. Pursuant to the Purchase Agreement, we had the right to sell and issue additional convertible notes up to an aggregate principal amount equal to $30.0 million, in addition to the $25.0 million initial principal amount of the Convertible Note.

Immediately prior to the completion of the Merger, the Convertible Note was converted into shares of Pre-Merger Oruka Common Stock based on the aggregate principal amount of $25.0 million, plus unpaid accrued interest of $1.5 million divided by the conversion price, which was determined based upon the Company’s fully-diluted capitalization immediately prior to the Merger. At the effective time of the Merger, the Pre-Merger Oruka Common Stock issued upon the conversion of the Convertible Note (including accrued interest) automatically converted into shares of Company Common Stock. 2,722,207 shares of Company Common Stock were issued on conversion of the Convertible Note and accrued interest. As of September 30, 2024, there is no note payable to a related party.

Critical Accounting Policies and Significant Judgments and Estimates

Our management’s discussion and analysis of its financial condition and results of operations is based on its financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues recognized and expenses incurred during the reporting periods. Our estimates are based on its historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our consolidated financial statements appearing elsewhere in this Quarterly Report, we believe the following accounting policies used in the preparation of our financial statements require the most significant judgments and estimates.

Accrued Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued research and development expenses. This process involves estimating the level of service performed and the associated cost incurred for the services when we have not yet been invoiced or otherwise notified of actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or

when contractual milestones are met; however, some require advance payments. We make estimates of our accrued expenses as of each balance sheet date in the financial statements based on facts and circumstances known to us at that time. At each period end, we corroborate the accuracy of these estimates with the service providers and make adjustments, if necessary. Estimated accrued research and development expenses include those related to fees paid to vendors in connection with discovery development activities and any research organizations in connection with studies and testing. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period.

Stock-Based Compensation

We measure stock options granted to employees and non-employees based on the estimated fair values of the awards as of the grant date using the Black-Scholes option-pricing model. The model requires management to make a number of assumptions, including common stock fair value, expected volatility, expected term, risk-free interest rate and expected dividend yield. For restricted stock awards and restricted stock units, the estimated fair value is the fair market value of the underlying stock on the grant date. We expense the fair value of our equity-based compensation awards on a straight-line basis over the requisite service period, which is the period in which the related services are received. We account for award forfeitures as they occur. The expense for stock-based awards with performance conditions is recognized when it is probable that a performance condition is met during the vesting period.

Determination of Fair Value of Common Stock

A public trading market for Company Common Stock has been established in connection with the completion of this Merger. As such, it is no longer necessary for our board of directors to estimate the fair value of our stock-based awards in connection with its accounting for granted stock-based awards or other such awards we may grant, as the fair value of Company Common Stock and share-based awards is determined based on the quoted market price of Company Common Stock.

Prior to the merger, Pre-Merger Oruka's common stock valuations were prepared using a hybrid method, including an option pricing method ("OPM"). The OPM treats common stock and preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, the common stock has value only if the funds available for distribution to stockholders exceed the value of the preferred stock liquidation preferences at the time of the liquidity event, such as a strategic sale or a merger. The hybrid method is a probability-weighted expected return method ("PWERM"), where the equity value in one or more of the scenarios is calculated using an OPM. The PWERM is a scenario-based methodology that estimates the fair value of common stock based upon an analysis of future values for the Company, assuming various outcomes. The common stock value is based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes available as well as the rights of each class of stock. The future value of the common stock under each outcome is discounted back to the valuation date at an appropriate risk-adjusted discount rate and probability weighted to arrive at an indication of value for the common stock. A discount for lack of marketability of the common stock is then applied to arrive at an indication of value for the common stock.

The assumptions underlying these valuations represented management's best estimate, which involved inherent uncertainties and the application of management's judgment. As a result, if Pre-Merger Oruka had used significantly different assumptions or estimates, the fair value of Pre-Merger Oruka's incentive shares and its stock-based compensation expense could have been materially different.

Recently Issued Accounting Pronouncements

See Note 2 to the condensed consolidated financial statements included in Part I - Item 1 of this Quarterly Report for more information regarding recently issued accounting pronouncements.

Off-Balance Sheet Arrangements

As of September 30, 2024, we did not have any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company, as defined by Rule 12b-2 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and in Item 10(f)(1) of Regulation S-K, and are not required to provide the information under this item.

Item 4. Controls and Procedures

Management's Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. Our 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 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.

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. As required by Rule 13a-15(b) or Rule 15d-15(b) promulgated by the Securities and Exchange Commission under the Exchange Act, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report. Based on the foregoing, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Quarterly Report at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the 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 legal proceedings relating to claims arising from the ordinary course of business. Our management believes that there are currently no claims or actions pending against us, the ultimate disposition of which could reasonably be expected to have a material adverse effect on our results of operations, financial condition or cash flows.

Item 1A. Risk Factors

Investing in shares of our common stock involves a high degree of risk. You should carefully consider the following risks and uncertainties, together with all of the other information contained in this Quarterly Report on Form 10-Q before making an investment decision. The occurrence of any of the following risks could materially and adversely affect our business, financial condition, reputation, or results of operations. In such case, the trading price of shares of our common stock could decline, and you may lose all or part of your investment. It is not possible to predict or identify all such risks; our operations could also be affected by factors, events or uncertainties that are not presently known to us or that we currently do not consider presenting significant risks to our operations. Therefore, you should not consider the following risks to be a complete statement of all the potential risks or uncertainties that we face.

RISK FACTOR SUMMARY

We are subject to a number of risks that if realized could materially harm our business, prospects, operating results, and financial condition. Some of the more significant risks and uncertainties we face include those summarized below. The summary below is not exhaustive and is qualified by reference to the full set of risk factors set forth in Item 1A of this Form 10-Q "Risk Factors". Please carefully consider all the information in this Form 10-Q, including the full set of risks set forth in the "Risk Factors" section, and in our other filings with the SEC before making an investment decision regarding the Company.

Risks Related to Our Financial Condition and Capital Requirements

- We are a preclinical stage biopharmaceutical company with a limited operating history on which to assess our business; we have not initiated, conducted or completed any clinical trials, and have no products approved for commercial sale.
- We have historically incurred losses and we anticipate that we will continue to incur losses for the foreseeable future.
- We have never generated revenue from product sales and may never be profitable.
- We may not be able to raise the capital that we need to support our business plans.
- Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Risks Related to Clinical Development and Regulatory Approval

- Drug development and obtaining and maintaining regulatory approval for drug products is costly, time-consuming, and highly uncertain.
- We are substantially dependent on the success of our two most advanced programs, ORKA-001 and ORKA-002, and our anticipated clinical trials of such programs may not be successful.
- We may not be able to meet requirements for the chemistry, manufacturing and control of our programs.
- We face competition from entities that have developed or may develop programs for the diseases addressed by product candidates developed by us.
- The United States Food and Drug Administration ("FDA") and comparable foreign regulatory approval processes are lengthy and time consuming and we may not be able to obtain or may be delayed in obtaining regulatory approvals for our product candidates.
- Even if we obtain regulatory approval, we will be subject to ongoing regulatory obligations.
- We may fail to achieve our projected development goals in the time frames we announce and expect.

Risks Related to Our Intellectual Property

- Our ability to obtain and protect our patents and other proprietary rights is uncertain.
- We may fail in obtaining or maintaining necessary rights to our programs.
- We may be subject to patent infringement claims or may need to file such claims.
- Our patents and our ability to protect our products may be impaired by changes to patent laws.
- Our patent protection could be reduced or eliminated for non-compliance with legal requirements.

- We may fail to identify or interpret relevant third-party patents.
- We may become subject to claims challenging the inventorship or ownership of our intellectual property.
- Patent terms may be inadequate to protect our competitive position of our programs.
- Our technology licensed from various third-parties may be subject to retained rights.

Risks Related to Our Reliance on Third Parties

- We currently rely on agreements with third parties to develop our product candidates. If we are unable to maintain collaborations or licensing arrangements, or if our collaborations or licensing arrangements are not successful, our business could be negatively impacted.
- Third parties we rely on for the execution of nonclinical studies and clinical trials may fail to carry out their contractual duties.
- We may be unable to use third-party manufacturing sites, our third-party manufacturers may encounter difficulties in production or we may need to switch or create third-party manufacturer redundancies.

Other Risk Factors - Risks Related to Employee Matters, Managing Growth, Other Risks Related to Our Business, and Owning Our Common Stock

- Our business is dependent on key personnel and we will be harmed if we cannot recruit and retain highly qualified personnel to successfully implement our business strategy.
- In order to successfully implement our plans and strategies, we will need to grow the size of our organization and we may experience difficulties in managing this growth.
- Our estimates of market opportunity and forecasts of market growth may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all.
- Significant disruptions of information technology systems or breaches of data security could adversely affect our business.
- Changes in and failures to comply with United States and foreign privacy and data protection laws, regulations and standards may adversely affect our business, operations and consolidated financial performance.
- We may become exposed to costly and damaging liability claims and our insurance may not cover all damages from such claims.
- Our business could be adversely affected by macroeconomic conditions.
- We do not anticipate paying any dividends in the foreseeable future.
- Future sales of shares by existing stockholders could cause our stock price to decline.
- Future sales and issuances of equity and debt could result in additional dilution to our stockholders and could cause our stock price to decline.

Risks Related to Our Financial Condition and Capital Requirements

We are a preclinical stage biopharmaceutical company with a limited operating history on which to assess our business; we have not initiated, conducted or completed any clinical trials, have no products approved for commercial sale, have historically incurred losses, and we anticipate that we will continue to incur significant losses for the foreseeable future. Moreover, we have never generated revenue from product sales and may never be profitable.

We are a preclinical stage biopharmaceutical company with a limited operating history. We will need to raise substantial additional capital to continue to fund our operations in the future. We have based our estimates on assumptions that may prove to be wrong, and could exhaust our available financial resources sooner than it currently anticipates.

We have devoted substantially all of our financial resources to identify, acquire, and develop our product candidates, organizing and staffing our company, and providing general and administrative support for our operations.

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We expect our losses to increase as our product candidates enter advanced clinical trials. It may be several years, if ever, before we complete pivotal clinical trials or have a product candidate approved for commercialization. We expect to invest significant funds into the research and development of our current programs to determine the potential to advance product candidates to regulatory approval. If we obtain regulatory approval to market a product candidate, our future revenue will depend upon the size of any markets in which our product candidates may receive approval, and our ability to achieve sufficient market acceptance, pricing, coverage and adequate reimbursement from third-party payors, and adequate market share for our product candidates in those markets. Even if we obtain adequate market share for our product candidates, we may never become profitable despite obtaining such market share and acceptance of our products.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future and our expenses will increase substantially if and as we:

- continue the preclinical development and initiate the clinical development of our product candidates;
- continue efforts to discover and develop new product candidates;
- continue the manufacturing of our product candidates or increase volumes manufactured by third parties;
- advance our product candidates into larger, more expensive clinical trials;
- initiate additional preclinical studies or clinical trials for our product candidates;

- seek regulatory and marketing approvals and reimbursement for our product candidates;
- establish a sales, marketing, and distribution infrastructure to commercialize any products for which it may obtain marketing approval and market for ourselves;
- make milestone, royalty, or other payments under third-party license agreements;
- seek to maintain, protect, and expand our intellectual property portfolio; and
- experience any delays or encounter issues with the development and potential regulatory approval of our clinical and product candidates such as safety issues, manufacturing delays, clinical trial accrual delays, longer follow-up for planned studies or trials, additional major studies or trials, or supportive trials necessary to support marketing approval.

We have no significant experience as a company in initiating, conducting or completing clinical trials. In part because of this lack of experience, we cannot be certain that our planned clinical trials will begin or be completed on time, if at all. In addition, we have not yet demonstrated an ability to obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history. Further, the net losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance.

We will need to continue to raise additional capital in order to fund our operations.

As of September 30, 2024, we had $410.9 million of cash. We have incurred significant net losses since our inception. We anticipate that we will continue to incur significant losses for the foreseeable future. Since February 6, 2024 (inception), we have incurred significant operating losses. For the period from February 6, 2024 (inception) to September 30, 2024, we reported a net loss of $57.9 million and net cash used from operating activities of $39.0 million. We will need to raise additional capital to continue to fund our operations and service our debt obligations in the future. Until such time, if ever, as we can generate substantial revenue from the sale of our product candidates, we expect to finance our cash needs through a combination of equity offerings, debt financings and licensing, development or collaboration agreements. If we are unable to raise additional capital when needed, that may raise substantial doubt about our ability to continue as a going concern. We expect that our existing cash as of $410.9 million as of September 30, 2024 will be sufficient to fund our operating expenses and capital expenditure requirements for at least 12 months from the date these condensed consolidated financial statements were issued.

Developing our product candidates and operating our company requires a substantial amount of capital. We expect our research and development expenses to increase in connection with our ongoing activities, particularly as we advance our product candidates through clinical trials. We may need to raise additional capital to fund our operations and such funding may not be available to us on acceptable terms, or at all, and such funding may become even more difficult to obtain. Competition for additional capital among biotechnology companies may be particularly intense during this period of economic instability. We may be unable to raise capital through public offerings of our common stock and may need to turn to alternative financing arrangements. Such arrangements, if we pursue them, could involve issuances of one or more types of securities, including common stock, preferred stock, convertible debt, warrants to acquire common stock or other securities. These securities could be issued at or below the then prevailing market price for our common stock. In addition, if we issue debt securities, the holders of the debt would have a claim to our assets that would be superior to the rights of stockholders until the principal, accrued and unpaid interest and any premium or make-whole has been paid. Interest on any newly-issued debt securities and/or newly-incurred borrowings would increase our operating costs and reduce our net income (or increase our net loss), and these impacts may be material. If the issuance of new securities results in diminished rights to holders of our common stock, the market price of our common stock could be materially and adversely affected.

We do not currently have any products approved for sale and do not generate any revenue from product sales. Accordingly, we expect to rely primarily on equity and/or debt financings to fund our continued operations. Our ability to raise additional funds will depend, in part, on the success of our preclinical studies and clinical trials and other product development activities, regulatory events, our ability to identify and enter into licensing or other strategic arrangements, and other events or conditions that may affect our value or prospects, as well as factors related to financial, economic and market conditions, many of which are beyond our control. There can be no assurances that sufficient funds will be available to us when required or on acceptable terms, if at all.

If we are unable to raise additional capital when required or on acceptable terms, we may be required to:

- significantly delay, scale back, or discontinue the development or commercialization of our product candidates;
- seek strategic partnerships, or amend existing partnerships, for research and development programs at an earlier stage than otherwise would be desirable or that we otherwise would have sought to develop independently, or on terms that are less favorable than might otherwise be available in the future;
- dispose of technology assets, or relinquish or license on unfavorable terms, our rights to technologies or any of our product candidates that we otherwise would seek to develop or commercialize ourselves;
- pursue the sale of the company to a third party at a price that may result in a loss on investment for our stockholders; or
- file for bankruptcy or cease operations altogether (and face any related legal proceedings).

Any of these events could have a material adverse effect on our business, operating results, and prospects.

Even if we are successful in raising new capital, we could be limited in the amount of capital we raise due to investor demand restrictions placed on the amount of capital we raise, or other reasons.

Raising additional capital may cause dilution to our stockholders, restrict our operations, or require us to relinquish rights.

To the extent that we raise additional capital through the sale of equity securities or convertible debt securities, the ownership interest of our

stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of holders of our 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 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 or other arrangements with third parties when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to third parties to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

To the extent that we raise additional capital through the sale of equity, including pursuant to any sales under convertible debt or other securities convertible into equity, the ownership interest of our stockholders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect the rights of our stockholders.

In September 2024, we entered into a Securities Purchase Agreement with certain new institutional and accredited investors, whereby the investors purchased an aggregate of 5,600,000 shares of Company Common Stock, 2,439 shares of Company Series A Preferred Stock and pre-funded warrants to purchase an aggregate of 680,000 shares of common stock for an aggregate purchase price of approximately $200.5 million. Each share of Company Series A Preferred Stock is convertible into 1,000 shares of Company Common Stock.

Debt financing, if available, would likely involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, making additional product acquisitions, or declaring dividends. If we raise additional funds through strategic collaborations or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates or future revenue streams or grant licenses on terms that are not favorable to us. We cannot assure you that we will be able to obtain additional funding if and when necessary to fund our entire portfolio of product candidates to meet our projected plans. If we are unable to obtain funding on a timely basis, we may be required to delay or discontinue one or more of our development programs or be unable to expand our operations or otherwise capitalize on potential business opportunities, which could materially harm our business, financial condition, and results of operations.

Risks Related to Clinical Development, Regulatory Approval and Commercialization

We face competition from entities that have developed or may develop programs for the diseases addressed by product candidates developed by us.

The development and commercialization of drugs is highly competitive. Product candidates developed by us, if approved, will face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration. We compete with a variety of biopharmaceutical companies as well as academic institutions, governmental agencies, and public and private research institutions, among others. Many of the companies with which we are currently competing or will compete against in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, clinical trials, regulatory approvals, and marketing than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industry may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites, recruiting participants for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our product candidates.

Our competitors have developed, are developing or will develop programs and processes competitive with our programs and processes. Competitive therapeutic treatments include those that have already been approved and accepted by the medical community and any new treatments. Our success will depend partially on our ability to develop and commercialize products that have a competitive safety, efficacy, dosing and/or presentation profile. Our commercial opportunity and success will be reduced or eliminated if competing products are safer, more effective, have a more attractive dosing profile or presentation or are less expensive than the products we develop, or if our competitors develop competing products or if biosimilars enter the market more quickly than we do and are able to gain market acceptance.

Our programs are in preclinical stages of development and may fail in development or suffer delays. We depend on the successful initiation and completion of clinical trials for our product candidates to advance our product development plans.

We have no products on the market, and all of our programs are in preclinical stages of development and have not been tested in humans. As a result, we expect it will be many years before we can obtain regulatory approval for and commercialize any product candidate, if ever. We have not yet demonstrated our ability to initiate or complete any clinical trials, obtain regulatory approvals, manufacture a clinical or commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. We must initiate and complete clinical trials that demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, and can take years to complete and is uncertain as to outcome. A failure of one or more of our clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for their products.

We may experience a number of unforeseen events during clinical trials, including the following:

- our product candidates may have undesirable side effects or unexpected characteristics, causing us or our investigators to suspend or terminate the trials;
- the supply of our clinical trial materials or other materials necessary to conduct clinical trials of our product candidates may be insufficient, delayed, does not meet agreed-upon specifications, or are otherwise inadequate for use in clinical trials;
- regulators or institutional review boards (“IRBs”), the FDA or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site; clinical trials of any product candidates may fail to show safety or efficacy, produce negative or inconclusive results, and we may decide, or regulators may require it, to conduct additional preclinical studies or clinical trials or we may decide to abandon product development programs;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and/or contract research organizations (“CROs”);

- clinical trial sites deviating from trial protocol or dropping out of a trial; we may elect to, or regulators, IRBs or ethics committees may require that we or our investigators, suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants in our trials are being exposed to unacceptable health risks;

- the number of subjects required for clinical trials of any product candidates may be larger than we anticipate, especially if regulatory bodies require completion of non-inferiority or superiority trials; enrollment in these clinical trials may be slower than we anticipate or subjects may drop out of these clinical trials or fail to return for post-treatment follow-up 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, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;

- the cost of clinical trials of any of our programs may be greater than we anticipate;

- reports from clinical testing of other therapies may raise safety or efficacy concerns about our programs;

- our failure to establish an appropriate safety profile for a product candidate based on clinical or preclinical data for such product candidates as well as data emerging from other therapies in the same class as our product candidates; and

- the FDA or other regulatory authorities may require us to submit additional data such as long-term toxicology studies, or impose other requirements before permitting us to initiate a clinical trial.

Commencing clinical trials in the United States is subject to acceptance by the FDA of an investigational new drug application ("IND"), biologics license application ("BLA") or similar application and finalizing the trial design based on discussions with the FDA and other regulatory authorities. In the event that the FDA requires us to complete additional preclinical studies or it is required to satisfy other FDA requests prior to commencing clinical trials, the start of our first clinical trials may be delayed. If our clinical trials do not produce favorable results, our ability to obtain regulatory approval for our product candidates may be adversely impacted. Moreover, the combined data from our trials maybe inconclusive or may not be sufficient to ultimately gain marketing approval from the FDA or other regulatory authorities. There are equivalent processes and risks applicable to clinical trial applications in other countries, including countries in the European Union ("EU").

In addition, because of the competitive landscape for immunology and inflammation (commonly referred to as "I&I") indications, we may also face competition for clinical trial enrollment. Clinical trial enrollment will depend on many factors, including if potential clinical trial participants choose to undergo treatment with approved products or enroll in competitors' ongoing clinical trials for programs that are under development for the same indications as our programs. An increase in the number of approved products for the indications we are targeting with our programs may further exacerbate this competition. Our inability to enroll a sufficient number of participants could, among other things, delay our development timeline, which may further harm our competitive position.

We may not have the financial resources to continue development of, or to modify existing or enter into new collaborations for, a product candidate if we experience any issues that delay or prevent regulatory approval of, or our ability to commercialize, our product candidates. Our inability to complete development of, or commercialize our product candidates, or significant delays in doing so, could have a material and adverse effect on our business, financial condition, results of operations and prospects.

We are substantially dependent on the success of our two most advanced programs, ORKA-001 and ORKA-002, and our anticipated clinical trials of such programs may not be successful.

Our future success is substantially dependent on our ability to develop and timely obtain marketing approval for, and then successfully commercialize, our two most advanced programs, ORKA-001 and ORKA-002. We are investing a majority of our efforts and financial resources into the research and development of these programs. We anticipate initiating a Phase 1 clinical trial in healthy volunteers of ORKA-001 in the first quarter of 2025 and of ORKA-002 in the second half of 2025, each subject to the filing of an IND or foreign equivalent and regulatory approval. The success of our programs is dependent on observing a longer half-life of our product candidates in humans than other extended half-life monoclonal antibodies ("mAbs") currently marketed and in development as we believe this longer half-life has the potential to result in a more favorable dosing schedule for our product candidates, assuming they successfully complete clinical development and obtain marketing approval. This is based in part on the assumption that the longer half-life we have observed in non-human primates ("NHPs") will translate into an extended half-life of our product candidates in humans. To the extent we do not observe this extended half-life in humans, it would significantly and adversely affect the clinical and commercial potential of our product candidates.

Our programs will require additional clinical development, evaluation of clinical, preclinical and manufacturing activities, product development, marketing approval in multiple jurisdictions, substantial investment and significant marketing efforts before we generate any revenues from product sales.

The success of our product candidates will depend on a variety of factors. We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any current or future collaborator.

If we do not achieve our projected development goals in the time frames we announce and expect, the development and potential commercialization of our product candidates may be delayed and our expenses may increase and, as a result, our business may be materially harmed and our stock price may decline.

From time to time, we estimate the timing of the anticipated accomplishment of various scientific, clinical, regulatory and other product development goals, which it sometimes refers to as milestones. These milestones may include the commencement or completion of scientific studies and clinical trials, such as the expected timing for the anticipated commencement of our Phase 1 studies, clinical trials in psoriasis ("PsO") and other target indications, as well as the submission of regulatory filings. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are and will be based on numerous assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, or at all, the development and potential commercialization of our product candidates may be delayed or never achieved and, as a result, our business may be materially harmed and our stock price may decline. Additionally, delays relative to our projected timelines are likely to cause overall expenses to increase, which may require us to raise additional capital sooner than expected and prior to achieving targeted development milestones.

Any drug delivery device that we may use to deliver our product candidates may have its own regulatory, development, supply and other risks.

We expect to deliver our product candidates via a drug delivery device, such as an injector or other delivery system. There may be unforeseen technical complications related to the development activities required to bring such a product to market, including primary container compatibility and/or dose volume requirements. Our product candidates may not be approved or may be substantially delayed in receiving approval if the devices that we choose to develop do not gain and/or maintain their own regulatory approvals or clearances. Where approval of the drug product and device is sought under a single application, the increased complexity of the review process may delay approval. In addition, some drug delivery devices are provided by single-source unaffiliated third-party companies. We may be dependent on the sustained cooperation and effort of those third-party companies both to supply the devices and, in some cases, to conduct the studies required for approval or other regulatory clearance of the devices. Even if approval is obtained, we may also be dependent on those third-party companies continuing to maintain such approvals or clearances once they have been received. Failure of third-party companies to supply the devices on time and in accordance with the agreed-upon specifications, to successfully complete studies on the devices in a timely manner, or to obtain or maintain required approvals or clearances of the devices could result in increased development costs, delays in or failure to obtain regulatory approval and delays in product candidates reaching patients.

Our approach to the discovery and development of our programs is unproven, and we may not be successful in our efforts to build a pipeline of programs with commercial value.

Our approach to the discovery and development of the research programs with respect to which we have the option to acquire intellectual property license rights to pursuant to those certain antibody discovery and option agreements by and among the Company, Paragon Therapeutics, Inc. and Paruka Holding, LLC (the "Option Agreements") and leverages clinically validated mechanisms of action and incorporates advanced antibody engineering to optimize half-life and other properties designed to overcome limitations of existing therapies. Our programs are purposefully designed to improve upon existing product candidates and products while maintaining the same, well-established mechanisms of action. However, the scientific research that forms the basis of our efforts to develop programs using half-life extension technologies is ongoing and may not result in viable programs. There is limited clinical data available on product candidates utilizing half-life extension technologies, especially in I&I indications, demonstrating whether they are safe or effective for long-term treatment in humans. The long-term safety and efficacy of these technologies and the extended half-life and exposure profile of our programs compared to currently approved products is unknown.

We may ultimately discover that utilizing half-life extension technologies for our specific targets and indications and any programs resulting therefrom does not possess certain properties required for therapeutic effectiveness. We currently have only preclinical data regarding the increased half-life properties of our programs and the same results may not be seen in humans. In addition, programs using half-life extension technologies may demonstrate different chemical and pharmacological properties in participants than they do in laboratory studies. This technology and any programs resulting therefrom may not demonstrate the same chemical and pharmacological properties in humans and may interact with human biological systems in unforeseen, ineffective or harmful ways.

In addition, we may in the future seek to discover and develop programs that are based on novel targets and technologies that are unproven. If our discovery activities fail to identify novel targets or technologies for drug discovery, or such targets prove to be unsuitable for treating human disease, we may not be able to develop viable additional programs. We and our existing or future collaborators may never receive approval to market and commercialize any product candidate. Even if we or an existing or future collaborator obtains regulatory approval, the approval may be for targets, disease indications or patient populations that are not as broad as we intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. If the products resulting from the research programs with respect to which we have the option to acquire intellectual property license rights to pursuant to the Option Agreements prove to be ineffective, unsafe or commercially unviable, such programs would have little, if any, value, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

Preclinical and clinical development involves a lengthy and expensive process that is subject to delays and uncertain outcomes, and results of earlier studies and trials may not be predictive of future clinical trial results. If our preclinical studies and clinical trials are not sufficient to support regulatory approval of any of our product candidates, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of such product candidate.

Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical studies and then conduct extensive clinical trials to demonstrate the safety and efficacy of such product candidate in humans. Our clinical trials may not be conducted as planned or completed on schedule, if at all, and failure can occur at any time during the preclinical study or clinical trial process.

Furthermore, a failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates. In addition, we expect to rely on participants to provide feedback on measures such as measures of quality of life, which are subjective and inherently difficult to evaluate. These measures can be influenced by factors outside of our control, and can vary widely from day-to-day for a particular participant, and from participant to participant and from site to site within a clinical trial.

We cannot be sure that the FDA will agree with our clinical development plan. We plan to use the data from our planned Phase 1 trials of our ORKA-001 and ORKA-002 programs in healthy volunteers to support Phase 2 trials in PsO and potentially other I&I indications. If the FDA requires us to conduct additional trials or enroll additional participants, our development timelines may be delayed. We cannot be sure that submission of an IND, BLA or similar application will result in the FDA or comparable foreign regulatory authorities, as applicable, allowing clinical trials to begin in a timely manner, if at all. Moreover, even if these trials begin, issues may arise that could cause regulatory authorities to suspend or terminate such clinical trials. Events that may prevent successful or timely initiation or completion of clinical trials include: inability to generate sufficient preclinical, toxicology or other *in vivo* or *in vitro* data to support the initiation or continuation of clinical trials; delays in reaching a consensus with regulatory authorities on study design or implementation of the clinical trials; delays or failure in obtaining regulatory authorization to commence a trial; delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites; delays in identifying, recruiting and training suitable clinical investigators; delays in obtaining required IRB approval at each clinical trial site; delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing; failure by our CROs, other third parties or us to adhere to clinical trial protocols; failure to perform in accordance with the FDA's or any other regulatory authority's current Good Clinical Practice requirements ("GCPs") or applicable regulatory guidelines in other countries; changes to the clinical trial protocols; clinical sites deviating from trial protocol or dropping out of a trial; changes in regulatory requirements and guidance that require amending or submitting new clinical protocols; selection of clinical endpoints that require prolonged periods of observation or analyses of resulting data; transfer of manufacturing processes to facilities operated by a contract manufacturing organization ("CMO") and delays or failure by our CMOs or us to make any necessary changes to such manufacturing process; and third parties being unwilling or unable to satisfy their contractual obligations to us.

We could also encounter delays if a clinical trial is suspended or terminated by it, by the IRBs of the institutions in which such clinical trials are being conducted, by the Data Safety Monitoring Board, if any, for such clinical trial or by the FDA or comparable foreign regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical trial 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 the programs, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. 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, if the results of these trials are not positive or are only moderately positive or if there are safety concerns, our business and results of operations may be adversely affected and we may need to adjust or abandon our business plans and we may incur significant additional costs.

If we encounter difficulties enrolling participants in our future clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient participant enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of participants who remain in the trial until conclusion. The enrollment of participants in future trials for any of our programs will depend on many factors, including if participants choose to enroll in clinical trials, rather than using approved products, or if our competitors have ongoing clinical trials for programs that are under development for the same indications as our programs, and participants instead enroll in such clinical trials. Even if we are able to enroll a sufficient number of participants for our clinical trials, it may have difficulty maintaining participants in our clinical trials. Our inability to enroll or maintain a sufficient number of participants would result in significant delays in completing clinical trials and increased development costs or may require us to abandon one or more clinical trials altogether.

Preliminary, "topline" or interim data from our clinical trials may change as more participant data becomes available and are subject to audit and verification procedures.

From time to time, we may publicly disclose preliminary or topline data from our preclinical studies and clinical trials, which are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data. We also make assumptions, estimations, calculations and conclusions as part of our analyses of these data without the opportunity to fully and carefully evaluate complete data. As a result, the preliminary or topline 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 or subsequently made subject to audit and verification procedures.

Any preliminary or topline data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data are subject to the risk that one or more of the clinical outcomes may materially change as participant enrollment continues and more participant data become available or as participants from our clinical trials continue other treatments. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular product candidate, the approvability or commercialization of the particular product candidate and our company in general. In addition, the information we choose to publicly disclose regarding a particular preclinical study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the preliminary, topline or interim data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Our clinical trials may reveal significant adverse events or undesirable side effects not seen in our preclinical studies and may result in a safety profile that could halt clinical development, inhibit regulatory approval or limit commercial potential or market acceptance of any of our product candidates.

Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects, adverse events or unexpected characteristics. While preclinical studies in NHPs conducted with respect to our programs have not shown any such characteristics to date, we have not yet initiated any clinical trials in humans. If significant adverse events or other side effects are observed in any of our future clinical trials, we may have difficulty recruiting participants to such trials, participants may drop out of the trials, or we may be required to abandon the trials or our development efforts of one or more programs altogether. We, the FDA or other applicable regulatory authorities, or an IRB, may suspend any clinical trials of any program at any time for various reasons, including a belief that subjects or patients in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential products developed in the biotechnology industry that initially showed therapeutic promise in early-stage studies and trials have later been found to cause side effects that prevented their further development. However, other potential products have shown side effects in preclinical studies, which side effects do not present themselves in clinical trials in humans. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of the approved product due to their tolerability versus other therapies. In addition, an extended half-life could prolong the duration of undesirable side effects, which could also inhibit market acceptance. Treatment-emergent adverse events could also affect participant recruitment or the ability of enrolled subjects to complete our clinical trials or could result in potential product liability claims. Potential side effects associated with our product candidates may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from our product candidates may not be normally encountered in the general patient population and by medical personnel. Any of these occurrences could harm our business, financial condition, results of operations and prospects significantly.

In addition, even if we successfully advance our product candidates or any future product candidates through clinical trials, such trials will only include a limited number of participants and limited duration of exposure to our product candidates. As a result, we cannot be assured that adverse effects of our product candidates will not be uncovered when a significantly larger number of participants are exposed to the product candidate after approval. Further, any clinical trials may not be sufficient to determine the effect and safety consequences of using our product candidates over a multi-year period.

If any of the foregoing events occur or if one or more of the research programs with respect to which we have the option to acquire intellectual property license rights to pursuant to the Option Agreements prove to be unsafe, our entire pipeline could be affected, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Because we have limited financial and managerial resources, we focus our research and development efforts on certain selected programs. For example, we are initially focused on our most advanced programs, ORKA-001 and ORKA-002. As a result, we may forgo or delay pursuit of opportunities with other programs that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which we would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Any approved products resulting from our current programs or any future program may not achieve adequate market acceptance among clinicians, patients, healthcare third-party payors and others in the medical community necessary for commercial success and we may not generate any future revenue from the sale or licensing of such products.

Even if regulatory approval is obtained for a product candidate resulting from one of our current or future programs, they may not gain market acceptance among physicians, patients, healthcare payors or the medical community. We may not generate or sustain revenue from sales of the product due to factors such as whether the product can be sold at a competitive cost and whether it will otherwise be accepted in the market. There are several approved products and product candidates in later stages of development for the treatment of PsO. However, our programs incorporate advanced antibody engineering to optimize the half-life and formulation of antibodies; to date, no such antibody has been approved by the FDA for the treatment of PsO. Market participants with significant influence over acceptance of new treatments, such as clinicians and third-party payors, may not adopt a biologic that incorporates half-life extension for our targeted indications, and we may not be able to convince the medical community and third-party payors to accept and use, or to provide favorable reimbursement for, any programs developed by us or our existing or future collaborators. An extended half-life may make it more difficult for patients to change treatments and there is a perception that half-life extension could exacerbate side effects, each of which may adversely affect our ability to gain market acceptance. Market acceptance of our product candidates will depend on many factors, including factors that are not within our control.

Sales of medical products also depend on the willingness of clinicians to prescribe the treatment. We cannot predict whether clinicians, clinicians' organizations, hospitals, other healthcare providers, government agencies or private insurers will determine that our product is safe, therapeutically effective, cost effective or less burdensome as compared with competing treatments. If any of our product candidates is approved but does not achieve an adequate level of acceptance by such parties, we may not generate or derive sufficient revenue from that product candidate and may not become or remain profitable.

Certain of our programs may compete with our other programs, which could negatively impact our business and reduce our future revenue.

We are developing product candidates for the same indication, PsO, and may in the future develop our programs for other I&I indications. Each such program targets a different mechanism of action. However, developing multiple programs for a single indication may negatively impact our business if the programs compete with each other. For example, if multiple programs are conducting clinical trials at the same time, they could compete for the enrollment of participants. In addition, if multiple product candidates are approved for the same indication, they may compete for market share, which could limit our future revenue.

We may conduct clinical trials for programs at sites outside the United States, and the FDA may not accept data from trials conducted in such locations.

We may choose to conduct one or more of our future clinical trials outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with ethical principles. The trial population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will depend upon the determination that the trials also complied with all applicable U.S. laws and regulations. If the FDA does not accept the data from any trial that we conduct outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and would delay or permanently halt our development of the applicable product candidates. Even if the FDA accepted such data, it could require us to modify our planned clinical trials to receive clearance to initiate such trials in the United States or to continue such trials once initiated.

Further, conducting clinical trials outside of the U.S. presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled participants in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs that could restrict or limit our ability to conduct our clinical trials, the administrative burdens of conducting clinical trials under multiple sets of foreign regulations, potential restrictions on data generated from the clinical trial, foreign exchange fluctuations, diminished protection of intellectual property in some countries, as well as political and economic risks relevant to foreign countries.

Risks Related to Government Regulation

The regulatory approval processes of the FDA and other comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.

The process of obtaining regulatory approvals, both in the United States and abroad, is unpredictable, expensive and typically takes many years following commencement of clinical trials, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Before obtaining regulatory approvals for the commercial sale of our product candidates, including our most advanced programs, ORKA-001 and ORKA-002, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our product candidates are both safe and effective for each targeted indication. Securing regulatory approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Further, our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval. The FDA and comparable foreign regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and

require additional preclinical, clinical or other data. Our product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including: the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials; we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for our proposed indication; the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval; serious and unexpected drug-related side effects may be experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates; we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh our safety risks; the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials; the data collected from clinical trials of our product candidates may not be acceptable or sufficient to support the submission of a BLA or other submission or to obtain regulatory approval in the United States or elsewhere, and we may be required to conduct additional clinical trials; the FDA or the applicable foreign regulatory authority may disagree regarding the formulation, labeling and/or the specifications of our product candidates; the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of drugs in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The 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.

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 trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, our product candidates and our ability to generate revenue will be materially impaired.

We may not be able to meet requirements for the chemistry, manufacturing and control of our programs.

In order to receive approval of our products by the FDA and comparable foreign regulatory authorities, we must show that we and our CMO partners are able to characterize, control and manufacture our drug products safely and in accordance with regulatory requirements. This includes manufacturing the active ingredient, developing an acceptable formulation, manufacturing the drug product, performing tests to adequately characterize the formulated product, documenting a repeatable manufacturing process, and demonstrating that our drug products meet stability requirements. Meeting these chemistry, manufacturing and control requirements is a complex task that requires specialized expertise. If we are not able to meet the chemistry, manufacturing and control requirements, we may not be successful in getting our products approved.

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

The Patient Protection and Affordable Act, as amended by the Healthcare and Education Reconciliation Act (the "ACA"), includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a highly similar or "biosimilar" product may not be submitted to the FDA until four years following the date that the reference product was first approved by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first approved. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product.

We believe that any of our product candidates approved as biologics under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any 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.

Even if we receive regulatory approval of our product candidates, we will be subject to extensive ongoing regulatory obligations and continued regulatory review and may result in restrictions on the use of the product, 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 may receive for our product candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the product candidate, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a risk evaluation and mitigation strategy ("REMS") in order to approve our product candidates, which could entail requirements for a medication guide, physician training and 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 comparable foreign regulatory authorities approve our product candidates, our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export will be subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable foreign regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as on-going compliance with current CGMPs and GCPs for any clinical trials that we conduct following approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with CGMPs.

If we or a regulatory authority discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing, restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials, restrictions on the manufacturing process, warning or untitled letters, civil and criminal penalties, injunctions, product seizures, detentions or import bans, voluntary or mandatory publicity requirements and imposition of restrictions on

operations, including costly new manufacturing requirements. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

We may face difficulties from healthcare legislative reform measures.

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

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, including conflicts of interest rules, which could expose us to penalties.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. Principal investigators for our clinical trials may serve as scientific advisors or consultants to us or may be affiliated with our other service providers, including CROs or site management organizations, and from time to time may receive cash compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity of the data generated at the applicable clinical trial site or in the applicable trial may be questioned or jeopardized.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. If our operations are found to be in violation of any of these laws or any other governmental laws and regulations that may apply to it, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. Further, defending against any such actions can be costly and time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

Even if we are able to commercialize any product candidates, due to unfavorable pricing regulations and/or third-party coverage and reimbursement policies, we may not be able to offer such product candidates at competitive prices which would seriously harm our business.

We intend to seek approval to market our product candidates in 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. Our ability to successfully commercialize any product candidates that we may develop will depend in part on the extent to which reimbursement for these product candidates and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. These entities may create preferential access policies for a competitor's product, including a branded or generic/biosimilar product, over our products in an attempt to reduce their costs, which may reduce our commercial opportunity. Additionally, if any of our product candidates are approved and we are found to have improperly promoted off-label uses of those product candidates, we may become subject to significant liability, which would materially adversely affect our business and financial condition.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to or from recipients in the public or private sector. We may engage third parties to sell our products outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenue, if any.

In some countries, particularly member states of the EU ("EU Member States"), the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a therapeutic. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU Member States and parallel distribution, or arbitrage between low-priced and high-priced EU Member States, can further reduce prices. To obtain coverage and reimbursement or pricing approvals in some countries, we or current or future collaborators may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of any product candidate approved for marketing is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business, financial condition, results of operations or prospects could be materially and adversely affected. Brexit could lead to legal uncertainty and potentially divergent national laws and regulations, including those related to the pricing of prescription pharmaceuticals, as the United Kingdom ("UK") determines which EU laws to replicate or replace. If the UK were to significantly alter its regulations affecting the pricing of prescription pharmaceuticals, we could face significant new costs.

A breakthrough therapy, fast track, or other expedited designation for our product candidates may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that those product candidates will receive marketing approval.

We may seek a breakthrough therapy, fast track, or other designation for appropriate product candidates. Designations such as these are within the discretion of the FDA, or other comparable regulatory authorities. The receipt of a designation for a product candidate may not result in a faster development process, review or approval compared to products considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualifies under one of FDA's designation programs, the FDA may later decide that the products no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Risks Related to Our Intellectual Property

Our ability to obtain and protect our patents and other proprietary rights is uncertain, exposing us to the possible loss of competitive advantage.

We rely upon a combination of patents, trademarks, trade secret protection, confidentiality agreements and the Option Agreements to protect the intellectual property related to our programs and technologies and to prevent third parties from competing unfairly with it. Our success depends in large part on our ability to obtain and maintain patent protection for our platform technologies, programs and their uses, as well as our ability to operate without infringing on or violating the proprietary rights of others. Paragon has filed provisional patent applications and intends to file one or more additional provisional patent applications directed to antibodies that target IL-23, including applications covering composition of matter, pharmaceutical formulations, and methods of using such antibodies, including ORKA-001. In addition, Paragon has filed provisional patent applications and intends to file one or more additional provisional patent applications directed to antibodies that target IL-17, including applications covering composition of matter, pharmaceutical formulations, and methods of using such antibodies, including ORKA-002. However, we may not be able to protect our intellectual property rights throughout the world and the legal systems in certain countries may not favor enforcement or protection of patents, trade secrets and other intellectual property. Filing, prosecuting and defending patents on programs worldwide would be expensive and our intellectual property rights in some foreign jurisdictions can be less extensive than those in the United States; the reverse may also occur. As such, we may not have patents in all countries or all major markets and may not be able to obtain patents in all jurisdictions even if we apply for them. Our competitors may operate in countries where we do not have patent protection and can freely use our technologies and discoveries in such countries to the extent such technologies and discoveries are publicly known or disclosed in countries where we do have patent protection or pending patent applications.

Our pending and future patent applications may not result in patents being issued. Any issued patents may not afford sufficient protection of our programs or their intended uses against competitors, nor can there be any assurance that the patents issued will not be infringed, designed around, invalidated by third parties, or effectively prevent others from commercializing competitive technologies, products or programs. Even if these patents are granted, they may be difficult to enforce. Further, any issued patents that we may license or own covering our programs could be narrowed or found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad, including the United States Patent and Trademark Office ("USPTO"). Further, if we encounter delays in our clinical trials or delays in obtaining regulatory approval, the period of time during which we could market our product candidates under patent protection would be reduced. Thus, the patents that we may own and license may not afford us any meaningful competitive advantage.

In addition to seeking patents for some of our technology and programs, we may also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. In order to protect our proprietary technology and processes, we rely in part on confidentiality agreements with our collaborators, employees, consultants, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. We may need to share our proprietary information, including trade secrets, 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 state actors and those affiliated with or controlled by state actors. In addition, while we undertake efforts to protect our trade secrets and other confidential information from disclosure, others may independently discover trade secrets and proprietary information, and in such cases, we may not be able to assert any trade secret rights against such party. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

Lastly, if our trademarks and trade names are not registered or 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 successful in obtaining or maintaining necessary rights to our programs through acquisitions and in-licenses.

Because our development programs currently do and may in the future require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license, or use these third-party proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our programs. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we do obtain, we may have to abandon development of the relevant program, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

While we plan to obtain the right to control prosecution, maintenance and enforcement of the patents relating to our programs, there may be times when the filing and prosecution activities for patents and patent applications relating to our programs are controlled by our current and future licensors or collaboration partners. If any of our current and future licensors or collaboration partners fail to prosecute, maintain and enforce such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patents covering our product candidates, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed to and from third parties, we

may still be adversely affected or prejudiced by actions or inactions of our licensees, our future licensors and our counsel that took place prior to the date upon which we assumed control over patent prosecution.

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

It is possible that we may be unable to obtain licenses at a reasonable cost or on reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to redesign our technology, programs, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations, and prospects significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, manufacturing methods, programs, or future methods or products resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

Disputes may arise between us and our future licensors regarding intellectual property subject to a license agreement, including: the scope of rights granted under the license agreement and other interpretation-related issues; whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement; our right to sublicense patents and other rights to third parties; our right to transfer or assign the license; the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our future licensors and us and our partners; and the priority of invention of patented technology.

We may be subject to patent infringement claims or may need to file claims to protect our intellectual property, which could result in substantial costs and liability and prevent us from commercializing our potential products.

Because the intellectual property landscape in the biotechnology industry is rapidly evolving and interdisciplinary, it is difficult to conclusively assess our freedom to operate and guarantee that we can operate without infringing on or violating third-party rights. If certain of our product candidates are ultimately granted regulatory approval, patent rights held by third parties, if found to be valid and enforceable, could be alleged to render one or more of our product candidates infringing. If a third party successfully brings a claim against us, we may be required to pay substantial damages, be forced to abandon any affected product candidate and/or seek a license from the patent holder. In addition, any intellectual property claims (e.g., patent infringement or trade secret theft) brought against us, whether or not successful, may cause us to incur significant legal expenses and divert the attention of our management and key personnel from other business concerns. We cannot be certain that patents owned or licensed by us will not be challenged by others in the course of litigation. Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise funds.

Competitors may infringe or otherwise violate our patents, trademarks, copyrights or other intellectual property. To counter infringement or other violations, we may be required to file claims, which can be expensive and time-consuming. Any such claims could provoke these parties to assert counterclaims against us, including claims alleging that we infringe their patents or other intellectual property rights. In addition, in a patent infringement proceeding, a court or administrative body may decide that one or more of the patents we assert is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to prevent the other party from using the technology at issue on the grounds that our patents do not cover the technology. Similarly, if we assert trademark infringement claims, a court or administrative body may determine that the marks we have asserted are invalid or unenforceable or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In such a case, we could ultimately be forced to cease use of such marks. In any intellectual property litigation, even if we are successful, any award of monetary damages or other remedy we receive may not be commercially valuable.

Further, we may be required to protect our patents through procedures created to attack the validity of a patent at the USPTO. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position. 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.

In addition, if our programs are found to infringe the intellectual property rights of third parties, these third parties may assert infringement claims against our future licensees and other parties with whom we have business relationships and we may be required to indemnify those parties for any damages they suffer as a result of these claims, which may require us to initiate or defend protracted and costly litigation on behalf of licensees and other parties regardless of the merits of such claims. If any of these claims succeed, we may be forced to pay damages on behalf of those parties or may be required to obtain licenses for the products they use.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

As is common in the biotechnology industry, in addition to our employees, we engage the services of consultants to assist us in the development of our programs. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other biotechnology or pharmaceutical companies including our competitors or potential competitors. We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of former employers or competitors. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may become subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor.

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

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

Changes in either the patent laws or interpretation of patent laws in the United States, including patent reform legislation such as the Leahy-Smith America Invents Act (the "Leahy-Smith Act") could increase the uncertainties and costs surrounding the prosecution of our owned and in-licensed patent applications and the maintenance, enforcement or defense of our owned and in-licensed issued patents. The Leahy-Smith Act includes a number of significant changes to United States patent law. These changes include provisions that affect the way patent applications are prosecuted, redefine prior art, provide more efficient and cost-effective avenues for competitors to challenge the validity of patents, and enable third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent at USPTO-administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith Act, the United States transitioned to a first-to-file system in which, assuming that the other statutory requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. As such, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. U.S. Supreme Court and U.S. Court of Appeals for the Federal Circuit rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations, including in the antibody arts. For example, the United States Supreme Court in *Amgen, Inc. v. Sanofi* (*Amgen*) recently held that Amgen's patent claims to a class of antibodies functionally defined by their ability to bind a particular antigen were invalid for lack of enablement where the patent specification provided twenty-six exemplary antibodies, but the claimed class of antibodies covered a "vast number" of additional antibodies not disclosed in the specification. The Court stated that if patent claims are directed to an entire class of compositions of matter, then the patent specification must enable a person skilled in the art to make and use the entire class of compositions. This decision makes it unlikely that we will be granted U.S. patents with composition of matter claims directed to antibodies functionally defined by their ability to bind a particular antigen. Even if we are granted claims directed to functionally defined antibodies, it is possible that a third party may challenge our patents, when issued, relying on the reasoning in *Amgen* or other recent precedential court decisions. Additionally, there have been proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to enforce our proprietary technology. This combination of events has created uncertainty with respect to the validity and enforceability of patents once obtained. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future.

Geopolitical instability in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of patent applications and the maintenance, enforcement or defense of issued patents. For example, the United States' and foreign governments' actions related to Russia's invasion of Ukraine may limit or prevent filing, prosecution and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an event were to occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022 allowing Russian companies and individuals to exploit inventions owned by patentees that have citizenship or nationality in, are registered in, or have predominately primary place of business or profit-making activities in the United States and other countries that Russia has deemed unfriendly without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

In addition, a European Unified Patent Court ("UPC") entered into force on June 1, 2023. The UPC is a common patent court that hears patent infringement and revocation proceedings effective for EU Member States. This could enable third parties to seek revocation of a European patent in a single proceeding at the UPC rather than through multiple proceedings in each of the jurisdictions in which the European patent is validated.

Although we do not currently own any European patents or applications, if we obtain such patents and applications in the future, any such revocation and loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and products. Moreover, the controlling laws and regulations of the UPC will develop over time, and may adversely affect our ability to enforce or defend the validity of any European patents we may obtain. We may decide to opt out from the UPC any future European patent applications that we may file and any patents we may obtain. If certain formalities and requirements are not met, however, such European patents and patent applications could be challenged for non-compliance and brought under the jurisdiction of the UPC. We cannot be certain that future European patents and patent applications will avoid falling under the jurisdiction of the UPC, if we decide to opt out of the UPC.

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

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

legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our programs, our competitive position would be adversely affected.

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

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect. For example, we may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third-party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications, or that we were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering products or technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could require us to obtain rights to issued patents covering such technologies.

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

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

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

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

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest United States non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Our technology licensed from various third parties may be subject to retained rights.

Our future licensors may retain certain rights under the relevant agreements with us, including the right to use the underlying technology for noncommercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse.

Risks Related to Our Reliance on Third Parties

We currently rely on licensing arrangements with Paragon through the Option Agreements. If we are unable to maintain collaborations or licensing arrangements, or if our collaborations or licensing arrangements are not successful, our business could be negatively impacted.

We currently rely on our licensing arrangements with Paragon through the Option Agreements for a substantial portion of our discovery capabilities and in-licenses.

Collaborations or licensing arrangements that we enter into may not be successful, and any success will depend heavily on the efforts and activities of such collaborators or licensors. If any of our current or future collaborators or licensors experience delays in performance of, or fails to perform our obligations under their agreement with us, disagrees with our interpretation of the terms of such agreement or terminates their agreement with us, the research programs with respect to which we have the option to acquire intellectual property license rights to pursuant to the Option Agreements and development timeline could be adversely affected. If we fail to comply with any of the obligations under our collaborations or license agreements, including payment terms and diligence terms, our collaborators or licensors may have the right to terminate such agreements, in which event we may lose intellectual property rights and may not be able to develop, manufacture, market or sell the products covered by our agreements or may face other penalties under our agreements. Our collaborators and licensors may also fail to properly maintain or defend the intellectual property we have licensed from them, if required by our agreement with them, or even infringe upon, our intellectual property rights, leading to the potential invalidation of our intellectual property or subjecting us to litigation or arbitration, any of which would be time-consuming and expensive and could harm our ability to commercialize our product candidates. In addition, collaborators could independently develop, or develop with third parties, products that compete directly

or indirectly with our programs and products if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours.

As part of our strategy, we plan to evaluate additional opportunities to enhance our capabilities and expand our development pipeline or provide development or commercialization capabilities that complement ours. We may not realize the benefits of such collaborations, alliances or licensing arrangements. 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 may face significant competition in attracting appropriate collaborators, and more established companies may also be pursuing strategies to license or acquire third-party intellectual property rights that we consider attractive. These companies may have a competitive advantage over us due to their size, financial resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Whether we reach a definitive agreement for a collaboration will depend upon, among other things, our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Collaborations are complex and time-consuming to negotiate, document and execute. In addition, consolidation among large pharmaceutical and biotechnology companies has reduced the number of potential future collaborators. We may not be able to negotiate additional collaborations on a timely basis, on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market.

We currently rely, and plan to rely in the future, on third parties to conduct and support our preclinical studies and clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.

We have utilized and plan to continue to utilize and depend upon independent investigators and collaborators, such as medical institutions, CROs, contract testing labs, CMOs and strategic partners, to supply, conduct and support our preclinical studies and clinical trials under agreements with us. We will rely heavily on these third parties over the course of our preclinical studies and clinical trials, and we control only certain aspects of their activities. As a result, we will have less direct control over the conduct, timing and completion of these preclinical studies and clinical trials and the management of data developed through preclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with GCP regulations, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our programs in clinical development. If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications or refuse to approve our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with products produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our clinical trials will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether they devote sufficient time and resources to our programs. These third parties may be involved in mergers, acquisitions or similar transactions and may have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could negatively affect their performance on our behalf and the timing thereof and could lead to products that compete directly or indirectly with our product candidates. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates.

In addition, we currently rely on foreign CROs and CMOs, including WuXi Biologics (Hong Kong) Limited and its affiliates ("WuXi Biologics") and will likely continue to rely on foreign CROs and CMOs in the future. WuXi is a subsidiary or affiliate of WuXi Biologics, which is identified in the proposed U.S. legislation known as the BIOSECURE Act as a biotechnology "company of concern." The current version of the BIOSECURE Act introduced in the House of Representatives would prohibit federal agencies from entering into procurement contracts with, as well as providing grants and loans to, an entity that uses biotechnology equipment or services from a biotechnology company of concern, and includes a grandfathering provision allowing biotechnology equipment and services provided or produced by named "biotechnology companies of concern" under a contract or agreement entered into before the effective date until January 1, 2032. The pathway and timing for the BIOSECURE Act or its provisions to become law are uncertain, although the bill was passed in the House of Representatives on September 9, 2024. Depending on whether the BIOSECURE Act becomes law, what the final language of the BIOSECURE Act includes, and how the law is interpreted by U.S. federal agencies, we could be potentially restricted from pursuing U.S. federal government business or grants in the future if we continue to use WuXi or other parties identified as "biotechnology companies of concern" beyond the grandfathering period. Foreign CMOs may be subject to U.S. legislation, including the proposed BIOSECURE bill, trade restrictions and other foreign regulatory requirements which could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material or have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies.

For example, the biopharmaceutical industry in China is strictly regulated by the Chinese government. Changes to Chinese regulations or government policies affecting biopharmaceutical companies are unpredictable and may have a material adverse effect on our collaborators in China which could have an adverse effect on our business, financial condition, results of operations and prospects. Evolving changes in China's public health, economic, political, and social conditions and the uncertainty around China's relationship with other governments, such as the United States and the UK, could also negatively impact our ability to manufacture our product candidates for our planned clinical trials or have an adverse effect on our ability to secure government funding, which could adversely affect our financial condition and cause it to delay our clinical development programs. Furthermore, if the BIOSECURE bill is passed and one or more of our collaborators in China, including WuXi Biologics, is deemed to be a biotechnology company of concern, our operations and financial condition may be negatively impacted as a result of any delays or increased costs arising from the trade restrictions and other foreign regulatory requirements affecting such collaborators. In addition, while we have established relationships with CROs and CMOs outside of China, moving to those suppliers in the event of a geopolitical instability affecting our collaborators in China could introduce delays into the development program.

We currently rely and expect to rely in the future on the use of manufacturing suites in third-party facilities or on third parties to

manufacture our product candidates, and we may rely on third parties to produce and process our products, if approved. Our business could be adversely affected if we are unable to use third-party manufacturing suites or if the third-party manufacturers encounter difficulties in production.

We do not currently own any facility that may be used as our clinical or commercial manufacturing and processing facility and must currently rely on CMOs to manufacture our product candidates. We have not yet caused any product candidates to be manufactured on a commercial scale and may not be able to do so for any of our product candidates, if approved. We currently have a sole source relationship for our supply of the ORKA-001 and ORKA-002 programs. If there should be any disruption in such supply arrangement, including any adverse events affecting our sole supplier, it could have a negative effect on the clinical development of our programs and other operations while we work to identify and qualify an alternate supply source. We may not control the manufacturing process of, and may be completely dependent on, our contract manufacturing partners for compliance with cGMP requirements and any other regulatory requirements of the FDA or comparable foreign regulatory authorities for the manufacture of our product candidates. Beyond periodic audits, we have limited control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any approval in the future, we may need to find alternative manufacturing facilities, which would require the incurrence of significant additional costs, delays, and materially adversely affect our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Similarly, our failure, or the failure of our CMOs, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or drugs and harm our business and results of operations.

Moreover, our CMOs may experience manufacturing difficulties due to resource constraints, supply chain issues, or as a result of labor disputes or unstable political environments. If any CMOs on which we will rely fail to manufacture quantities of our product candidates at quality levels necessary to meet regulatory requirements and at a scale sufficient to meet anticipated demand at a cost that allows us to achieve profitability, our business, financial condition and prospects could be materially and adversely affected. In addition, our CMOs are responsible for transporting temperature-controlled materials that can be inadvertently degraded during transport due to several factors, rendering certain batches unsuitable for trial use for failure to meet, among others, our integrity and purity specifications. We and any of our CMOs may also face product seizure or detention or refusal to permit the import or export of products. Our business could be materially adversely affected by business disruptions to our third-party providers that could materially adversely affect our anticipated timelines, potential future revenue and financial condition and increase our costs and expenses. Each of these risks could delay or prevent the completion of our preclinical studies and clinical trials or the approval of any of our product candidates by the FDA, result in higher costs or adversely impact commercialization of our product candidates.

Risks Related to Employee Matters, Managing Growth and Other Risks Related to Our Business

In order to successfully implement our plans and strategies, we will need to grow the size of our organization and we may experience difficulties in managing this growth.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of preclinical and clinical drug development, technical operations, clinical operations, regulatory affairs and, potentially, sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial personnel and systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team working together in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel.

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

We are a preclinical stage biotechnology company with a limited operating history. We have been and will continue to be highly dependent on the research and development, clinical and business development expertise of our executive officers, as well as the other principal members of our management, scientific and clinical team. Any of our management team members may terminate their employment with us at any time. We do not maintain “key person” insurance for any of our executives or other employees.

Attracting and retaining qualified personnel will also be critical to our success, including with respect to any strategic transaction that we may pursue. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. 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 skills and experience required to successfully develop, facilitate regulatory approval of and commercialize product candidates. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions.

In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our discovery and nonclinical and clinical development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

Our future growth may depend, in part, on our ability to operate in foreign markets, where it would be subject to additional regulatory burdens and other risks and uncertainties.

Our future growth may depend, in part, on our ability to develop and commercialize our product candidates in foreign markets for which we may rely on collaboration with third parties. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the applicable foreign regulatory authority, and may never receive such regulatory approval for any of our product candidates. To obtain separate regulatory approval in many other countries, we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions. If we fail to comply with the regulatory requirements in international markets and 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 and our business will be

adversely affected. Moreover, even if we obtain approval of our product candidates and ultimately commercializes our product candidates in foreign markets, we would be subject to the risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and reduced protection of intellectual property rights in some foreign countries.

Our estimates of market opportunity and forecasts of market growth may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all.

Our market opportunity estimates and growth forecasts are subject to significant uncertainty and are based on assumptions and estimates which may not prove to be accurate. Our estimates and forecasts relating to size and expected growth of our target market may prove to be inaccurate. Even if the markets in which we compete meet our size estimates and growth forecasts, our business may not grow at similar rates, or at all. Our growth is subject to many factors, including our success in implementing our business strategy, which is subject to many risks and uncertainties.

Our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to obtain coverage and reimbursement and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved.

Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, CMOs, suppliers and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, CMOs, suppliers and vendors acting for or on our behalf may engage in misconduct or other improper activities. We have adopted a code of conduct and ethics, but it is not always possible to identify and deter misconduct by these 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 these laws or regulations.

Our internal information technology systems, or those of any of our CROs, manufacturers, other contractors or consultants, third-party service providers, or potential future collaborators, may fail or suffer security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations.

In the ordinary course of our business, we and the third parties upon which we rely collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) proprietary, confidential, and sensitive data, including personal data, intellectual property, trade secrets, and other sensitive data (collectively, sensitive information).

Despite the implementation of security measures in an effort to protect systems that store our information, given their size and complexity and the increasing amounts of information maintained on our internal information technology systems and those of our third-party CROs, other contractors (including sites performing our clinical trials), third-party service providers and supply chain companies, and consultants, these systems are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners and/or other third parties, or from cyber-attacks by malicious third parties, which may compromise our system infrastructure or lead to the loss, destruction, alteration or dissemination of, or damage to, our data.

Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, and the third parties upon which we rely, may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services. In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to provide our products or services, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

To the extent that any disruption or security breach were to result in loss, destruction, unavailability, alteration or dissemination of, or damage to, our data or applications, or for it to be believed or reported that any of these occurred, we could incur liability and reputational damage and the development and commercialization of our product candidates could be delayed. Further, our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption in, or failure or security breach of, our systems or third-party systems where information important to our business operations or commercial development is stored.

Our fully-remote workforce may create additional risks for our information technology systems and data because our employees work remotely and utilize network connections, computers, and devices working at home, while in transit and in public locations. Additionally, 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.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We may be unable in the future to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences.

We rely on third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts. 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 our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to it, 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' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; management distraction; delays; and other similar harms. Security incidents and attendant consequences may cause stakeholders (including investors and potential customers) to stop supporting our platform, deter new customers from products, and negatively impact our ability to grow and operate our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

We are subject to stringent and changing laws, regulations and standards, and contractual obligations relating to privacy, data protection, and data security. The actual or perceived failure to comply with such obligations could lead to government enforcement actions (which could include civil or criminal penalties), fines and sanctions, private litigation and/or adverse publicity and could negatively affect our operating results and business.

We and third parties who we work with are or may become subject to numerous domestic and foreign laws, regulations, and standards relating to privacy, data protection, and data security, the scope of which is changing, subject to differing applications and interpretations, and may be inconsistent among countries, or conflict with other rules. We are or may become subject to the terms of contractual obligations related to privacy, data protection and data security. Our obligations may also change or expand as our business grows. The actual or perceived failure by us or third parties related to us to comply with such laws, regulations and obligations could increase our compliance and operational costs, expose us to regulatory scrutiny, actions, fines and penalties, result in reputational harm, lead to a loss of customers, result in litigation and liability, and otherwise cause a material adverse effect on our business, financial condition, and results of operations.

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations may involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

We may be subject to adverse legislative or regulatory tax changes that could negatively impact our financial condition.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which may have retroactive application) could adversely affect our stockholders or us. We continue to assess the impact of various tax reform proposals and modifications to existing tax treaties in all jurisdictions where we have operations or employees to determine the potential effect on our business and any assumptions we make about our future taxable income. We cannot predict whether any specific proposals will be enacted, the terms of any such proposals or what effect, if any, such proposals would have on our business if they were to be enacted. For example, the United States enacted the Inflation Reduction Act of 2022, which implements, among other changes, a 1% excise tax on certain stock buybacks. In addition, beginning in 2022, the Tax Cuts and Jobs Act eliminated the previously available option to deduct research and development expenditures and requires taxpayers to amortize them generally over five years for research activities conducted in the United States and over 15 years for research activities conducted outside the United States. The U.S. Congress is considering legislation that would restore the current deductibility of research and development expenditures; however, there is no assurance that the current provision will be repealed or otherwise modified. Such changes, among others, may adversely affect our effective tax rate, results of operation and general business condition.

We may acquire businesses or products, or form strategic alliances, in the future, and may not realize the benefits of such acquisitions.

We may acquire additional businesses or products, form strategic alliances, or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new product candidates or products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. There is no assurance that, following any such acquisition, we will achieve the synergies expected in order to justify the transaction, which could result in a material adverse effect on our business and prospects.

We maintain our cash at financial institutions, often in balances that exceed federally-insured limits. The failure of financial institutions could adversely affect our ability to pay our operational expenses or make other payments.

Our cash held in non-interest-bearing and interest-bearing accounts exceeds the Federal Deposit Insurance Corporation ("FDIC") insurance limits. If such banking institutions were to fail, we could lose all or a portion of those amounts held in excess of such insurance limitations. For example, the FDIC took control of Silicon Valley Bank on March 10, 2023. The Federal Reserve subsequently announced that account holders would be made whole. We currently hold a small portion of our cash and cash equivalents at Silicon Valley Bank. However, the FDIC may not make all account holders whole in the event of future bank failures. In addition, even if account holders are ultimately made whole with respect to a future bank failure, account holders' access to their accounts and assets held in their accounts may be substantially delayed. Any material loss that we may experience in the future or inability for a material time period to access our cash and cash equivalents could have an adverse effect on our ability to pay our operational expenses or make other payments, which could adversely affect our business.

General Risk Factors

Our estimates of market opportunity and forecasts of market growth may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all.

Our market opportunity estimates and growth forecasts are subject to significant uncertainty and are based on assumptions and estimates which may not prove to be accurate. Our estimates and forecasts relating to size and expected growth of our target market may prove to be inaccurate. Even if the markets in which we compete meet our size estimates and growth forecasts, our business may not grow at similar rates, or at all. Our growth is subject to many factors, including our success in implementing our business strategy, which is subject to many risks and uncertainties.

Our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to obtain coverage and reimbursement and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved.

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

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing, and use of pharmaceutical products. While we currently have no products that have been approved for commercial sale, the future use of a product candidate in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims may be made by patients that use the product, healthcare providers, pharmaceutical companies, or others selling such product. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially and adversely affect the market for our products or any prospects for commercialization of our products. Although we intend to obtain product liability insurance for our future clinical trials, it is possible that any liabilities could exceed our insurance coverage or that in the future we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

Litigation costs and the outcome of litigation could have a material adverse effect on our business.

From time to time we may be subject to litigation claims through the ordinary course of our business operations regarding, but not limited to, employment matters, security of patient and employee personal information, contractual relations with collaborators and intellectual property rights. Litigation to defend ourselves against claims by third parties, or to enforce any rights that we may have against third parties, may continue to be necessary, which could result in substantial costs and diversion of our resources, causing a material adverse effect on our business, financial condition, results of operations or cash flows.

Our business could be adversely affected by economic downturns, inflation, fluctuation in interest rates, natural disasters, public health crises, political crises, geopolitical events, or other macroeconomic conditions, which could have a material and adverse effect on our results of operations and financial condition.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including, among other things, diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, increases in inflation rates, fluctuation in interest rates, and uncertainty about economic stability. For example, the COVID-19 pandemic resulted in widespread unemployment, economic slowdown and extreme volatility in the capital markets. The Federal Reserve previously raised interest rates multiple times in response to concerns about inflation and it may raise them again. Fluctuation in interest rates, coupled with reduced government spending and volatility in financial markets, may increase economic uncertainty and affect consumer spending. Similarly, the ongoing military conflict between Russia and Ukraine and in the Middle East and rising tensions with China have created extreme volatility in the global capital markets and may have further global economic consequences, including disruptions of the global supply chain. Any such volatility and disruptions may adversely affect our business or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more costly, more dilutive, or more difficult to obtain in a timely manner or on favorable terms, if at all. Increased inflation rates can adversely affect us by increasing our costs, including materials, operational, labor and employee benefit costs.

We may in the future experience disruptions as a result of such macroeconomic conditions, including delays or difficulties in initiating or expanding clinical trials and manufacturing sufficient quantities of materials. Any one or a combination of these events could have a material and adverse effect on our results of operations and financial condition.

Risks Related to Owning Our Stock

The market price of our common stock may continue to be volatile.

The market price of our common stock may be subject to significant fluctuations. Some of the factors that may cause the market price of our common stock to fluctuate include:

- timing and results of clinical trials and preclinical studies of our product candidates, or those of our competitors or our existing or future collaborators;
- failure to meet or exceed financial and development projections that we may provide to the public;
- announcements of significant or potential equity or debt sales by us;
- failure to meet or exceed the financial and development projections of the investment community;
- failure to achieve the perceived benefits of our recent merger as rapidly or to the extent anticipated by financial or industry analysts;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;

- actions taken by regulatory agencies with respect to our product candidates, clinical studies, manufacturing process or sales and marketing terms;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- additions or departures of key personnel, including scientific or management personnel;
- significant lawsuits, including patent or stockholder litigation;
- if securities or industry analysts do not publish research or reports about our business, or if they issue adverse or misleading opinions regarding our business and stock;
- changes in the market valuations of similar companies;
- general market, macroeconomic or geopolitical conditions or market conditions in the pharmaceutical and biotechnology sectors;
- sales of securities by us or our securityholders in the future;
- if we fail to raise an adequate amount of capital to fund our operations or continued development of our product candidates;
- trading volume of our common stock;
- announcements by competitors of new commercial products, clinical progress or lack thereof, significant contracts, commercial relationships or capital commitments;
- adverse publicity relating to precision medicine product candidates, including with respect to other products in such markets;

- the introduction of technological innovations or new therapies that compete with our products; and
- period-to-period fluctuations in our financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock. In addition, a recession, depression or other sustained adverse market event could materially and adversely affect our business and the value of our common stock. In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against such companies.

Furthermore, market volatility may lead to increased shareholder activism if we experience a market valuation that activists believe is not reflective of our intrinsic value. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our board of directors could have an adverse effect on our operating results, financial condition and cash flows.

Our certificate of incorporation and bylaws, as well as provisions under Delaware law, could make an acquisition of the company more difficult and may prevent attempts by our stockholders to replace or remove management.

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

- establish a classified board of directors such that all members of the board are not elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on at stockholder meetings;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call a special meeting of stockholders;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 66 2/3% of the votes that all stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law ("DGCL"), which prohibits stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us. Although we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders.

Our governing documents provide that, unless we consent in writing to the selection of an alternative forum, certain designated courts will be the sole and exclusive forum for certain legal actions 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, employees or agents.

Our governing documents provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of or based on a breach of a fiduciary duty owed by any of our current or former directors, officers, or other employees or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL, the certificate of incorporation or the bylaws, (iv) any action to interpret, apply, enforce or determine the validity of the certificate of incorporation or bylaws, or (v) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein, which for purposes of this risk factor refers to herein as the "Delaware Forum Provision." Our governing documents further provide that, unless we consent in writing to an alternative forum, the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, which for purposes of this risk factor refers to herein as the "Federal Forum Provision." Neither the Delaware Forum Provision nor the Federal Forum Provision will apply to any causes of action arising under the Exchange Act. In addition, any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and consented to the foregoing Delaware Forum Provision and Federal Forum Provision; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the U.S. federal securities laws and the rules and regulations thereunder.

The Delaware Forum Provision and the Federal Forum Provision may impose additional litigation costs on our stockholders in pursuing any such claims, particularly if such stockholders do not reside in or near the State of Delaware. Additionally, these forum selection clauses may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders.

Future sales of shares by existing stockholders could cause our stock price to decline.

If our stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after legal restrictions on resale lapse, the trading price of our common stock could decline. In addition, shares of our common stock that are subject to our outstanding options will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements and Rules 144 and 701 under the Securities Act.

We do not anticipate that we will pay any cash dividends in the foreseeable future

We do not anticipate that we will pay any cash dividends in the foreseeable future. The current expectation is that we will retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain, if any, for the foreseeable future.

Our executive officers, directors and principal stockholders have the ability to control or significantly influence all matters submitted to our stockholders for approval.

Our executive officers, directors and principal stockholders beneficially own a significant percentage of our outstanding common stock. As a result, if these stockholders were to choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these stockholders, if they choose to act together, would control or significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent our acquisition on terms that other stockholders may desire.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that equity research analysts publish about us and our business. Equity research analysts may elect to not provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. If we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause our stock price or trading volume to decline.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Trading Plans

During the quarter ended September 30, 2024, no director or Section 16 officer adopted or terminated any Rule 10b5-1 trading arrangements or non-Rule 10b5-1 trading arrangements (in each case, as defined in Item 408(a) of Regulation S-K).

Item 6. Exhibits.

The exhibits filed or furnished as part of this Quarterly Report are set forth below.

EXHIBIT NUMBER	DESCRIPTION	FORM	EXHIBIT	FILING DATE
2.1†	Agreement and Plan of Merger and Reorganization, dated as of April 3, 2024, by and among ARCA biopharma, Inc., Atlas Merger Sub Corp., Atlas Merger Sub II, LLC and Oruka Therapeutics, Inc.	8-K	2.1	April 3, 2024
3.1	Amended and Restated Certificate of Incorporation of the Company, filed September 3, 2024.	8-K	3.5	September 5, 2024
3.2	Amended and Restated Bylaws of the Company.	8-K	3.6	September 5, 2024
3.4	Form of Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock.	S-1/A	3.1(b)	May 24, 2013
3.5	Certificate of Elimination of Series A Convertible Preferred Stock , effective August 29, 2024.	8-K	3.8	September 5, 2024
3.6	Certificate of Designation of Preferences, Rights and Limitations of Series B Non-Voting Convertible Preferred Stock.	8-K	3.9	September 5, 2024
3.7	Certificate of Designation of Preferences, Rights and Limitations of Series A Non-Voting Convertible Preferred Stock.	8-K	3.1	September 13, 2024
4.1	Investor Rights Agreement, dated March 6, 2024, by and among Oruka Therapeutics, Inc. and certain parties thereto.	S-4	4.3	May 14, 2024
4.2	Form of Pre-Funded Warrant.	8-K	4.1	September 13, 2024
10.1	Form of Amendment to Oruka Subscription Agreement.	8-K	10.1	July 9, 2024
10.2	Form of Amended & Restated Oruka Subscription Agreement.	8-K	10.2	July 9, 2024
10.3	Asset Purchase Agreement, dated August 14, 2024, by and between ARCA biopharma, Inc. and Genvara Biopharma, Inc.	8-K	10.1	August 15, 2024
10.4*	Form of Registration Rights Agreement, dated as of August 29, 2024.			Filed herewith
10.5	Securities Purchase Agreement, dated September 11, 2024, by and between the Company and each purchaser identified on Annex A thereto.	8-K	10.1	September 13, 2024
10.6	Form of Registration Rights Agreement, dated as of September 13, 2024.	8-K	10.2	September 13, 2024
10.7†#	Consulting Agreement, effective as of August 30, 2024, by and between the Company and Jeff Dekker.	8-K	10.25	September 5, 2024
31.1*	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) promulgated under the Securities Exchange Act of 1934			
31.2*	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) promulgated under the Securities Exchange Act of 1934			
32.1**	Certification of the Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350 and Rule 13a-14(B) promulgated under the Securities Exchange Act of 1934			
101.INS	Inline XBRL Instance Document			
101.SCH	Inline XBRL Taxonomy Extension Schema with Embedded Linkbases Document			
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.			
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.			
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.			
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.			
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)			

* Filed herewith.

** Furnished herewith. The certifications on Exhibit 32.1 hereto are deemed not “filed” for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that Section. Such certifications will not be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

# Indicates management contract or compensatory plan.

† Exhibits and/or schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Company hereby undertakes to furnish supplementally copies of any of the omitted exhibits and schedules upon request by the SEC; provided, however, that the Company may request confidential treatment pursuant to Rule 24b-2 under the Exchange Act for any exhibits or schedules so furnished. Certain portions of this exhibit (indicated by “[***]”) have been omitted because they are both (i) not material and (ii) is the type of information that the registrant both customarily and actually treats as private and confidential.

SIGNATURES

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

Oruka Therapeutics, Inc.

Date: November 13, 2024

By: /s/ Lawrence Klein, PhD.
Lawrence Klein, PhD.
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 13, 2024

By: /s/ Arjun Agarwal
Arjun Agarwal
Senior Vice President, Finance
(Principal Financial Officer and
Principal Accounting Officer)

Exhibit 10.4

REGISTRATION RIGHTS AGREEMENT

This Registration Rights Agreement (this " **Agreement**") is made and entered into as of August 29, 2024, among Oruka Therapeutics, Inc., a Delaware corporation (the "**Company**"), ARCA biopharma, Inc. ("**Parent**"), a Delaware corporation, and each of the several purchasers signatory hereto (each such purchaser, a "**Purchaser**" and, collectively, the "**Purchasers**").

WHEREAS, the Company is party to that certain Agreement and Plan of Merger by and among the Company, Atlas Merger Sub Corp, a Delaware corporation ("**First Merger Sub**"), Atlas Merger Sub II, LLC, a Delaware limited liability company (" **Second Merger Sub**"), and Parent, dated as of April 3, 2024 (the "**Merger Agreement**"), pursuant to which (i) First Merger Sub will merge with and into the Company, with the Company becoming a wholly-owned subsidiary of Parent, and (ii) the Company will merge with and into Second Merger Sub, with Second Merger Sub being the surviving entity of the Second Merger (together, the "**Merger**");

WHEREAS, following the Effective Time (as defined in the Merger Agreement), Parent will change its name to Oruka Therapeutics, Inc. ("**TopCo**");

WHEREAS, the Company and the Purchasers are parties to an Amended and Restated Subscription Agreement, dated as of July 3, 2024 (as amended and restated to date, the "**Purchase Agreement**"), pursuant to which the Purchasers, severally and not jointly, are purchasing, prior to the Effective Time (as defined in the Merger Agreement), (i) shares of Common Stock (the "**Purchased Shares**") and (ii) if applicable, pre-funded warrants to acquire shares of Common Stock (the "**Pre-Funded Warrants**"); and

WHEREAS, in connection with the consummation of the transactions contemplated by the Purchase Agreement, and pursuant to the terms of the Purchase Agreement, the parties desire to enter into this Agreement in order to grant certain rights to the Purchasers as set forth below.

NOW, THEREFORE, in consideration of the covenants and promises set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereby agree as follows:

1. Definitions.

In addition to the terms defined herein, capitalized terms used and not otherwise defined herein that are defined in the Purchase Agreement shall have the meanings given such terms in the Purchase Agreement. As used in this Agreement, the following terms shall have the following meanings:

"**Advice**" shall have the meaning set forth in Section 6(c).

"**Company**" means Oruka Therapeutics, Inc. for all periods prior to the Effective Time and TopCo for all periods following the Effective Time.

"**Effectiveness Date**" means, with respect to the Initial Registration Statement required to be filed hereunder, the 90th calendar day following the date hereof (or, in the event of a "full review" by the Commission, the 120th calendar day following the date hereof) and with respect to any additional Registration Statements that may be required pursuant to Sections 2(b) and 2(c) or Section 3(c), the 45th calendar day following the date on which an additional Registration Statement is required to be filed hereunder (or, in the event of a "full review" by the Commission, the 60th calendar day following the date thereof); provided, however, that in the event the Company is notified by the Commission (orally or in writing) that one or more of the above Registration Statements will not be reviewed or is no longer subject to further review and comments, the Effectiveness Date as to such Registration Statement shall be the fifth (5th) Trading Day following the date on which the Company is so notified if such date precedes the dates otherwise required above, provided, further, if such Effectiveness Date falls on a day that is not a Trading Day, then the Effectiveness Date shall be the next succeeding Trading Day.

"**Effectiveness Period**" shall have the meaning set forth in Section 2(a).

"**Filing Date**" means, with respect to the Initial Registration Statement required hereunder, the 45th calendar day following the date hereof and, with respect to any additional Registration Statements that may be required pursuant to Sections 2(b) and 2(c) or Section 3(c), the 30th calendar day following the date on which the Company is permitted by SEC Guidance to file such additional Registration Statement related to the Registrable Securities.

"**Holder**" or "**Holders**" means the holder or holders, as the case may be, from time to time of Registrable Securities.

"**Indemnified Party**" shall have the meaning set forth in Section 5(c).

"**Indemnifying Party**" shall have the meaning set forth in Section 5(c).

"**Initial Registration Statement**" means the initial Registration Statement filed pursuant to this Agreement.

"**Losses**" shall have the meaning set forth in Section 5(a).

"**Plan of Distribution**" shall have the meaning set forth in Section 2(a).

"**Prospectus**" means the prospectus included in a Registration Statement (including, without limitation, a prospectus that includes any information previously omitted from a prospectus filed as part of an effective registration statement in reliance upon Rule 430A promulgated by the Commission pursuant to the Securities Act), as amended or supplemented by any prospectus supplement, with respect to the terms of the offering of any portion of the Registrable Securities covered by a Registration Statement, and all other amendments and supplements to the Prospectus, including post-effective amendments, and all material incorporated by reference or deemed to be incorporated by reference in such Prospectus.

"**Registrable Securities**" means, as of any date of determination, (a) all shares of TopCo common stock issued to the Purchasers at the closing of the Merger in respect of the Purchased Shares or issuable upon exercise of the Pre-Funded Warrants (collectively, the "**Purchase Agreement Securities**"), (b) all shares of TopCo issued at the closing of the Merger to the Purchasers in respect of all other shares of capital stock of the Company held by Purchaser as of immediately prior to the Effective Time (as defined in the Merger Agreement), (c) all shares of Parent common stock held by Purchaser as of immediately prior to the Effective Time, if any, and (d) any securities issued or then issuable upon any stock split, dividend or other distribution, recapitalization or similar event with respect to the foregoing; provided, however, that any such Registrable Securities shall cease to be

Registrable Securities (and the Company shall not be required to maintain the effectiveness of any, or file another, Registration Statement hereunder with respect thereto) upon the earliest to occur of (i) a Registration Statement with respect to the sale of such Registrable Securities is declared effective by the Commission under the Securities Act and such Registrable Securities have been disposed of by the Holder in accordance with such effective Registration Statement, (ii) such Registrable Securities have been previously sold in accordance with Rule 144, (iii) such securities become eligible for resale without volume or manner-of-sale restrictions pursuant to Rule 144 and without the requirement for the Company to be in compliance with the current public information requirement under Rule 144, as reasonably determined by counsel to the Company in accordance with Section 2(a) and (iv) five (5) years after the date of this Agreement.

"**Registration Statement**" means any registration statement required to be filed hereunder pursuant to Section 2(a) and any additional registration statements contemplated by Section 2(c) or Section 3(c), including (in each case) the Prospectus, amendments and supplements to any such registration statement or Prospectus, including pre- and post-effective amendments, all exhibits thereto, and all material incorporated by reference or deemed to be incorporated by reference in any such registration statement.

"**Rule 415**" means Rule 415 promulgated by the Commission pursuant to the Securities Act, as such Rule may be amended or interpreted from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same purpose and effect as such Rule.

"**Rule 424**" means Rule 424 promulgated by the Commission pursuant to the Securities Act, as such Rule may be amended or interpreted from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same purpose and effect as such Rule.

"**SEC Guidance**" means (i) any publicly-available written or oral guidance of the Commission staff, or any comments, requirements or requests of the Commission staff (whether or not publicly-available); provided, that any such oral guidance, comments, requirements or requests are reduced to writing by the Commission (and shared with the Purchasers if not publicly-available) and (ii) the Securities Act.

"**Selling Stockholder Questionnaire**" shall have the meaning set forth in Section 3(a).

"**Trading Day**" means any day on which the Parent common stock is traded on a National Exchange.

2. Shelf Registration.

(a) On or prior to each Filing Date, the Company shall prepare and file with the Commission a Registration Statement covering the resale of all of the Registrable Securities that are not then registered on an effective Registration Statement for an offering to be made on a continuous basis pursuant to Rule 415. Each Registration Statement filed hereunder shall be on Form S-3 (except if the Company is not then eligible to register for resale the Registrable Securities on Form S-3, in which case such registration shall be on another appropriate form in accordance with the provisions of Section 2(d)), and shall contain (unless otherwise directed by Holders holding at least 85% of Registrable Securities) disclosure substantially in the form of the "**Plan of Distribution**" attached hereto as Annex A and substantially in the form of the "**Selling Stockholder**" section attached hereto as Annex B. Subject to the terms of this Agreement, the Company shall use commercially reasonable efforts to cause a Registration Statement filed under this Agreement (including, without limitation, under Section 3(c)) to be declared effective under the Securities Act as promptly as possible after the filing thereof, but in any event no later than the applicable Effectiveness Date, and shall use its reasonable best efforts to keep such Registration Statement continuously effective under the Securities Act until the earlier of (a) the date that all Registrable Securities covered by such Registration Statement (i) have been sold, thereunder or pursuant to Rule 144, or (ii) may be sold without volume or manner-of-sale restrictions pursuant to Rule 144 and without the requirement for the Company to be in compliance with the current public information requirement under Rule 144, as reasonably determined by the counsel to the Company pursuant to a written opinion letter to such effect, addressed and acceptable to the Company's transfer agent and the affected Holders and (b) five (5) years after the date of this Agreement (the "**Effectiveness Period**"). The Company shall telephonically request effectiveness of a Registration Statement as of 5:00 p.m. (New York City time) on a Trading Day. The Company shall notify the Holders via e-mail of the effectiveness of a Registration Statement promptly following confirmation of effectiveness with the Commission. The Company shall, in accordance with SEC Guidance, promptly file a final Prospectus with the Commission as required by Rule 424 by 9:00 a.m. on the second (2^{nd}) Trading Day following the date each Registration Statement is declared effective.

(b) Notwithstanding the registration obligations set forth in Section 2(a), if the Commission informs the Company that all of the Registrable Securities cannot, as a result of the application of Rule 415 or other SEC Guidance, be registered for resale as a secondary offering on a single registration statement, the Company agrees to promptly inform each of the Holders thereof and use commercially reasonable efforts to file amendments to the Initial Registration Statement as required by the Commission, covering the maximum number of Registrable Securities permitted to be registered by the Commission, on Form S-3 or such other form available to register for resale the Registrable Securities as a secondary offering; with respect to filing on Form S-3 or other appropriate form; provided, however, that prior to filing such amendment, the Company shall be obligated to use commercially reasonable efforts to advocate with the Commission for the registration of all of the Registrable Securities in accordance with the SEC Guidance.

(c) Notwithstanding any other provision of this Agreement, if the Commission or any SEC Guidance sets forth a limitation on the number of Registrable Securities permitted to be registered on a particular Registration Statement as a secondary offering, including as a result of the application of Rule 415 (and notwithstanding that the Company used commercially reasonable efforts to advocate with the Commission for the registration of all or a greater portion of Registrable Securities), unless otherwise directed in writing by a Holder as to its Registrable Securities, the total number of Registrable Securities to be registered on such Registration Statement will be reduced as follows:

a. First, the Company shall reduce Registrable Securities represented by shares of Common Stock other than the Purchase Agreement Securities (applied, in the case that some but not all of such shares of Common Stock may be registered, to the Holders on a pro rata basis based on the total number of such unregistered shares of Common Stock held by such Holders, but excluding from such pro rata calculation any unregistered shares of Common Stock held by a Holder that the SEC has deemed to be an "underwriter" or otherwise requires such Holder to sell its shares of Common Stock in a primary offering); and

b. Second, the Company shall reduce Registrable Securities represented by the Purchase Agreement Securities (applied, in the case that some but not all of Purchase Agreement Securities may be registered, to the Holders on a pro rata basis based on the total number of unregistered Purchase Agreement Securities held by such Holders, but excluding from such pro rata calculation any unregistered shares of Common Stock held by a Holder that the SEC has deemed to be an "underwriter" or otherwise requires such Holder to sell its shares of Common Stock in a primary offering).

In the event of a cutback hereunder, the Company shall give the Holder at least two (2) Trading Days prior written notice along with the calculations as to such Holder's allotment. In the event the Company amends the Initial Registration Statement in accordance with the foregoing, the Company will use its commercially reasonable efforts to file with the Commission, as promptly as allowed by the Commission or SEC Guidance provided to the Company or to registrants of securities in general, one (1) or more registration statements on Form S-3 or such other form available to register for resale those Registrable Securities that were not registered for resale on the Initial Registration Statement, as amended.

(d) If Form S-3 is not available for the registration of the resale of Registrable Securities hereunder, the Company shall (i) register the resale of the Registrable Securities on another appropriate form and (ii) undertake to register the Registrable Securities on Form S-3 as soon as such form is available, provided that the Company shall maintain the effectiveness of the Registration Statement then in effect until such time as a Registration Statement on Form S-3 covering the Registrable Securities has been declared effective by the Commission.

3. Registration Procedures.

In connection with the Company's registration obligations hereunder, the Company shall:

(a) Not less than five (5) Trading Days prior to the filing of each Registration Statement and not less than one (1) Trading Day prior to the filing of any related Prospectus or any amendment or supplement thereto (including any document that would be incorporated or deemed to be incorporated therein by reference), the Company shall (i) furnish to each Holder copies of all such documents proposed to be filed, which documents (other than those incorporated or deemed to be incorporated by reference) will be subject to the review of such Holders, and (ii) use commercially reasonable efforts to cause its officers and directors, counsel and independent registered public accountants to respond to such inquiries as shall be necessary, in the reasonable opinion of respective counsel to each Holder, to conduct a reasonable investigation within the meaning of the Securities Act. The Company shall not file a Registration Statement or any such Prospectus or any amendments or supplements thereto to which the Required Holders (as defined below) shall reasonably object in good faith, provided that, the Company is notified of such objection in writing no later than three (3) Trading Days after the Holders have been so furnished copies of a Registration Statement or one (1) Trading Day after the Holders have been so furnished copies of any related Prospectus or amendments or supplements thereto. Each Holder agrees to furnish to the Company a completed questionnaire in the form attached to this Agreement as Annex C or such other form as reasonably acceptable to the Company (a "**Selling Stockholder Questionnaire**") on a date that is not less than two (2) Trading Days prior to the Filing Date or by the end of the third (3rd) Trading Day following the date on which such Holder receives draft materials in accordance with this Section 3. The Company shall not be required to include any Registrable Securities in the Registration Statement for any Holder that has not provided such Selling Stockholder Questionnaire.

(b) (i) Prepare and file with the Commission such amendments, including post-effective amendments, to a Registration Statement and the Prospectus used in connection therewith as may be necessary to keep a Registration Statement continuously effective as to the applicable Registrable Securities for the Effectiveness Period and prepare and file with the Commission such additional Registration Statements in order to register for resale under the Securities Act all of the Registrable Securities, (ii) cause the related Prospectus to be amended or supplemented by any required Prospectus supplement (subject to the terms of this Agreement), and, as so supplemented or amended, to be filed pursuant to Rule 424, (iii) respond as promptly as reasonably possible to any comments received from the Commission with respect to a Registration Statement or any amendment thereto and provide as promptly as reasonably possible to the Holders true and complete copies of all correspondence from and to the Commission relating to a Registration Statement (provided that, the Company shall excise any information contained therein that would constitute material non-public information regarding the Company or any of its subsidiaries), and (iv) comply in all material respects with the applicable provisions of the Securities Act and the Exchange Act with respect to the disposition of all Registrable Securities covered by a Registration Statement during the applicable period in accordance (subject to the terms of this Agreement) with the intended methods of disposition by the Holders thereof set forth in such Registration Statement as so amended or in such Prospectus as so supplemented.

(c) If, during the Effectiveness Period, the number of Registrable Securities at any time exceeds 100% of the number of shares of Common Stock then registered in a Registration Statement, then the Company shall, subject to Sections 2(b) and 2(c), if applicable, file as soon as reasonably practicable, an additional Registration Statement covering the resale by the Holders of not less than the number of such Registrable Securities.

(d) Notify the Holders of Registrable Securities to be sold (which notice shall, pursuant to clauses (iii) through (v) hereof, be accompanied by an instruction to suspend the use of the Prospectus until the requisite changes have been made) as promptly as reasonably possible (and, in the case of (i)(A) below, not less than one (1) Trading Day prior to such filing) and (if requested by any such Person) confirm such notice in writing no later than one (1) Trading Day following the day (i)(A) when a Prospectus or any Prospectus supplement or post-effective amendment to a Registration Statement is proposed to be filed, (B) when the Commission notifies the Company whether there will be a "review" of such Registration Statement and whenever the Commission comments in writing on such Registration Statement, and (C) with respect to a Registration Statement or any post-effective amendment, when the same has become effective, (ii) of any request by the Commission or any other federal or state governmental authority for amendments or supplements to a Registration Statement or Prospectus or for additional information, (iii) of the issuance by the Commission or any other federal or state governmental authority of any stop order suspending the effectiveness of a Registration Statement covering any or all of the Registrable Securities or the initiation of any Proceeding for that purpose, (iv) of the receipt by the Company of any notification with respect to the suspension of the qualification or exemption from qualification of any of the Registrable Securities for sale in any jurisdiction, or the initiation or threatening of any action, suit, proceeding, inquiry or investigation before or brought by any Governmental Entity (a "**Proceeding**") for such purpose, and (v) of the occurrence of any event or passage of time that makes the financial statements included in a Registration Statement ineligible for inclusion therein or any statement made in a Registration Statement or Prospectus or any document incorporated or deemed to be incorporated therein by reference untrue in any material respect or that requires any revisions to a Registration Statement, Prospectus or other documents so that, in the case of a Registration Statement or the Prospectus, as the case may be, it will not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading; provided, however, that in no event

shall any such notice contain any information that would constitute material, non-public information regarding the Company or any of its subsidiaries.

(e) Use its commercially reasonable efforts to avoid the issuance of, or, if issued, obtain the withdrawal of (i) any order stopping or suspending the effectiveness of a Registration Statement, or (ii) any suspension of the qualification (or exemption from qualification) of any of the Registrable Securities for sale in any jurisdiction, at the earliest practicable moment.

(f) If requested by a Holder, furnish to each Holder, without charge, an electronic copy of the conformed copy of each such Registration Statement and each amendment thereto, including financial statements and schedules, all documents incorporated or deemed to be incorporated therein by reference to the extent requested by such Person, and all exhibits to the extent requested by such Person (including those previously furnished or incorporated by reference) promptly after the filing of such documents with the Commission, provided that any such item that is available on the EDGAR system (or successor thereto) need not be furnished.

(g) Subject to the terms of this Agreement, the Company hereby consents to the use of such Prospectus and each amendment or supplement thereto by each of the selling Holders in connection with the offering and sale of the Registrable Securities covered by such Prospectus and any amendment or supplement thereto, except after the giving of any notice pursuant to Section 3(d).

(h) Prior to any resale of Registrable Securities by a Holder, use its commercially reasonable efforts to register or qualify or cooperate with the selling Holders in connection with the registration or qualification (or exemption from the registration or qualification) of such Registrable Securities for the resale by the Holder under the securities or Blue Sky laws of such jurisdictions within the United States as any Holder reasonably requests in writing, to keep each registration or qualification (or exemption therefrom) effective during the Effectiveness Period and to do any and all other acts or things reasonably necessary to enable the disposition in such jurisdictions of the Registrable Securities covered by each Registration Statement, provided that the Company shall not be required to qualify generally to do business in any jurisdiction where it is not then so qualified, subject the Company to any material tax in any such jurisdiction where it is not then so subject or file a general consent to service of process in any such jurisdiction.

(i) If requested by a Holder, promptly (and in any event within five (5) Trading Days of such request) deliver to Holder certificates or book entry statements, as applicable, representing Registrable Securities to be delivered to a transferee pursuant to an effective Registration Statement, which certificates shall be free of all restrictive legends (and have its counsel provide such opinions that such restrictive legends need not appear on such certificates as may be reasonably requested), and to enable such Registrable Securities to be in such denominations and registered in the name of the transferee as such Holder may reasonably request. If requested by a Holder other than in connection with a transfer pursuant to an effective registration statement, promptly (and in any event within five (5) Trading Days of such request) deliver to Holder certificates or book entry statements, as applicable, representing Registrable Securities to be delivered to a transferee, which certificates shall be free of all restrictive legends, and to enable such Registrable Securities to be in such denominations and registered in such names as any such Holder may reasonably request; provided that Holder timely furnishes to Company a completed Holder Representation Letter in substantially the form attached hereto as Annex D and such other customary representations as may be reasonably required, in accordance with Applicable Law, in connection therewith.

(j) Upon the occurrence of any event contemplated by Section 3(d)(iii) through (v), as promptly as reasonably possible under the circumstances taking into account the Company's good faith determination of any adverse consequences to the Company and its stockholders of the premature disclosure of such event, prepare a supplement or amendment, including a post-effective amendment, to a Registration Statement or a supplement to the related Prospectus or any document incorporated or deemed to be incorporated therein by reference, and file any other required document so that, as thereafter delivered, neither a Registration Statement nor such Prospectus will contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading. If the Company notifies the Holders in accordance with clauses (iii) through (v) of Section 3(d) above to suspend the use of any Prospectus until the requisite changes to such Prospectus have been made, then the Holders shall suspend use of such Prospectus; provided that the Company shall only be entitled to exercise its right under this Section 3(j) to suspend the availability of a Registration Statement and Prospectus up to two (2) occasions in any twelve (12)-month period for a period not to exceed forty-five (45) consecutive days or a total of ninety (90) calendar days, in each case in any such twelve (12)-month period. The Company will use its reasonable best efforts to ensure that the use of the Prospectus may be resumed as promptly as is reasonably practicable.

(k) Otherwise use commercially reasonable efforts to comply with all applicable rules and regulations of the Commission under the Securities Act and the Exchange Act, including, without limitation, Rule 172 under the Securities Act, file any final Prospectus, including any supplement or amendment thereof, with the Commission pursuant to Rule 424 under the Securities Act, promptly inform the Holders in writing if, at any time during the Effectiveness Period, the Company does not satisfy the conditions specified in Rule 172 and, as a result thereof, the Holders are required to deliver a Prospectus in connection with any disposition of Registrable Securities and take such other actions as may be reasonably necessary to facilitate the registration of the Registrable Securities hereunder.

(l) The Company shall use its commercially reasonable efforts to maintain eligibility for use of Form S-3 (or any successor form thereto) for the registration of the resale of the Registrable Securities once eligible to use such form.

(m) The Company may require each selling Holder to furnish to the Company a certified statement as to the number of shares of Common Stock beneficially owned by such Holder and, if required by the Commission, the natural persons thereof that have voting and dispositive control over the shares.

(n) The Company shall use its reasonable best efforts to cause all Registrable Securities to be listed on each securities exchange or market, if any, on which the shares of Parent common stock are listed.

(o) The Company shall, at its sole expense, upon appropriate notice from a Holder stating that Registrable Securities have been sold or transferred pursuant to an effective Registration Statement, promptly (and in any event within five (5) Trading Days of such notice) prepare and deliver certificates or evidence of book-entry positions representing the Registrable Securities to be delivered to a transferee pursuant to such Registration Statement, which certificates or book-entry positions shall be free of any restrictive legends and in such denominations and registered in such names as the undersigned may request.

(p) Neither the Company nor any subsidiary or affiliate thereof shall identify any Holder as an underwriter in any public disclosure or filing with the Commission or any trading market; provided, that if the Commission requires that a Holder be identified as a statutory underwriter in a Registration Statement, such Holder will have the option, in its sole and absolute discretion, to either (i) withdraw from such Registration Statement upon its prompt written request to the Company, in which case the Company's obligation to register such Holder's Registrable Securities will be deemed satisfied or (ii) be included as such in such Registration Statement; provided, further, that the foregoing shall not prohibit the Company from including the disclosure found in the "**Plan of Distribution**" section attached hereto as Exhibit A in the Registration Statement.

(q) Once a Registration Statement covering the resale of the Registrable Securities is declared effective, the Company shall remove all restrictive legends on Purchase Agreement Securities, and the Company shall, upon request of the Purchaser or the Transfer Agent, provide a blanket opinion of counsel permitting such removal. Further, the Company shall remove all restrictive legends, (i) following any sale of Purchase Agreement Securities pursuant to Rule 144 or any other applicable exemption from the registration requirements of the Securities Act, or (ii) if such Purchase Agreement Securities are eligible for resale under Rule 144(b)(1) or any successor provision. Without limiting the foregoing, upon request of the Purchaser, subject to receipt by the Company of an opinion of counsel reasonably satisfactory to the Company to the effect that such legend is no longer required under the Securities Act, the Company shall promptly cause the legend to be removed from any book-entry statements for any Purchase Agreement Securities in accordance with the terms of this Agreement and deliver, or cause to be delivered, to any Purchaser new book-entry statements representing the Purchase Agreement Securities that are free from all restrictive and other legends or, at the request of such Purchaser, via DWAC transfer to such Purchaser's account.

4. Registration Expenses. All fees and expenses incident to the performance of or compliance with this Agreement by the Company shall be borne by the Company whether or not any Registrable Securities are sold pursuant to a Registration Statement. The fees and expenses referred to in the foregoing sentence shall include, without limitation, (i) all registration and filing fees (including, without limitation, fees and expenses of the Company's counsel and independent registered public accountants) (A) with respect to filings made with the Commission, (B) with respect to filings required to be made with any National Exchange on which the Common Stock is then listed for trading, and (C) in compliance with applicable state securities or Blue Sky laws reasonably agreed to by the Company in writing (including, without limitation, fees and disbursements of counsel for the Company in connection with Blue Sky qualifications or exemptions of the Registrable Securities), (ii) printing expenses (including, without limitation, expenses of printing certificates for Registrable Securities), (iii) messenger, telephone and delivery expenses, (iv) fees and disbursements of counsel for the Company, (v) Securities Act liability insurance, if the Company so desires such insurance, (vi) fees and expenses of all other Persons retained by the Company in connection with the consummation of the transactions contemplated by this Agreement, including the Company's transfer agent, and (vii) solely in connection with the review and filing of the initial Registration Statement, the reasonable fees and expenses, not to exceed $35,000, of one counsel for the selling Holders selected by the Holders of a majority of the Registrable Securities to be registered. In addition, the Company shall be responsible for all of its internal expenses incurred in connection with the consummation of the transactions contemplated by this Agreement (including, without limitation, all salaries and expenses of its officers and employees performing legal or accounting duties), the expense of any annual audit and the fees and expenses incurred in connection with the listing of the Registrable Securities on any securities exchange as required hereunder. In no event shall the Company be responsible for any underwriting, broker or similar fees or commissions of any Holder or, except to the extent provided for in the Purchase Agreement or this Agreement, any legal fees or other costs of the Holders.

5. Indemnification.

(a) Indemnification by the Company. The Company shall, notwithstanding any termination of this Agreement, indemnify and hold harmless each Holder and its affiliates, the officers, directors, members, partners, agents, brokers (including brokers who offer and sell Registrable Securities as principal as a result of a pledge or any failure to perform under a margin call of Common Stock), investment advisors and employees (and any other Persons with a functionally equivalent role of a Person holding such titles, notwithstanding a lack of such title or any other title) of each of them, each Person who controls any such Holder (within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act) and the officers, directors, members, stockholders, partners, agents and employees (and any other Persons with a functionally equivalent role of a Person holding such titles, notwithstanding a lack of such title or any other title) of each such controlling Person, to the fullest extent permitted by applicable law, from and against any and all losses, claims, damages, liabilities, costs (including, without limitation, reasonable and documented attorneys' fees) and expenses (collectively, "**Losses**"), as incurred, arising out of or based solely upon (1) any untrue or alleged untrue statement of a material fact contained in a Registration Statement, any Prospectus or any form of prospectus or in any amendment or supplement thereto or in any preliminary prospectus, or arising out of or relating to any omission or alleged omission of a material fact required to be stated therein or necessary to make the statements therein (in the case of any Prospectus or supplement thereto, in light of the circumstances under which they were made) not misleading or (2) any violation or alleged violation by the Company of the Securities Act, the Exchange Act or any state securities law, or any rule or regulation thereunder, in connection with the performance of its obligations under this Agreement, except to the extent, but only to the extent, that (i) such untrue statements or omissions are based solely upon information regarding such Holder furnished in writing to the Company by such Holder expressly for use therein, or to the extent that such information relates to such Holder or such Holder's proposed method of distribution of Registrable Securities and was reviewed and expressly approved in writing by such Holder expressly for use in a Registration Statement, such Prospectus or in any amendment or supplement thereto (it being understood that the Holder has approved Annex A hereto for this purpose) or (ii) in the case of an occurrence of an event of the type specified in Section 3(d)(iii)-(v), the use by such Holder of an outdated, defective or otherwise unavailable Prospectus after the Company has notified such Holder in writing that the Prospectus is outdated, defective or otherwise unavailable for use by such Holder and prior to the receipt by such Holder of the Advice contemplated in Section 6(c). The Company shall notify the Holders promptly of the institution, threat or assertion of any Proceeding arising from or in connection with the transactions contemplated by this Agreement of which the Company is aware. Such indemnity shall remain in full force and effect regardless of any investigation made by or on behalf of such indemnified person and shall survive the transfer of any Registrable Securities by any of the Holders in accordance with Section 6(f).

(b) Indemnification by Holders. Each Holder shall, severally and not jointly, indemnify and hold harmless the Company, its directors, officers, agents and employees, each Person who controls the Company (within the meaning of Section 15 of the Securities Act and Section 20 of the Exchange Act), and the directors, officers, agents or employees of such controlling Persons, to the fullest extent permitted by applicable law, from and against all Losses, as incurred, to the extent arising out of or based solely upon any untrue or alleged untrue statement of a material fact contained in any Registration Statement, any Prospectus, or in any amendment or supplement thereto or in any preliminary prospectus, or arising out of or relating to any omission or alleged omission of a material fact required to be stated therein or necessary to make the statements therein (in the case of any Prospectus or supplement thereto, in the light of the circumstances under which they were made) not misleading to the extent, but only to the extent, that such untrue statement or omission is contained in any information so furnished in writing by such Holder to the Company expressly for inclusion in such Registration Statement or such Prospectus, including information provided in the

Selling Stockholder Questionnaire or regarding the proposed method of distribution of Registrable Securities that was reviewed and expressly approved in writing by such Holder expressly for use in a Registration Statement (it being understood that the Holder has approved Annex A hereto for this purpose), such Prospectus or in any amendment or supplement thereto. In no event shall the liability of a selling Holder be greater in amount than the dollar amount of the proceeds (net of all expenses paid by such Holder in connection with any claim relating to this Section 5 and the amount of any damages such Holder has otherwise been required to pay by reason of such untrue statement or omission) received by such Holder upon the sale of the Registrable Securities included in the Registration Statement giving rise to such indemnification obligation.

(c) Conduct of Indemnification Proceedings. If any Proceeding shall be brought or asserted against any Person entitled to indemnity hereunder (an "**Indemnified Party**"), such Indemnified Party shall promptly notify the Person from whom indemnity is sought (the " **Indemnifying Party**") in writing, and the Indemnifying Party shall have the right to assume the defense thereof, including the employment of counsel reasonably satisfactory to the Indemnified Party and the payment of all reasonable fees and expenses incurred in connection with defense thereof, provided that the failure of any Indemnified Party to give such notice shall not relieve the Indemnifying Party of its obligations or liabilities pursuant to this Agreement, except (and only) to the extent that it shall be finally determined by a court of competent jurisdiction (which determination is not subject to appeal or further review) that such failure shall have materially and adversely prejudiced the Indemnifying Party.

An Indemnified Party shall have the right to employ separate counsel in any such Proceeding and to participate in the defense thereof, but the fees and expenses of such counsel shall be at the expense of such Indemnified Party or Parties unless: (1) the Indemnifying Party has agreed in writing to pay such fees and expenses, (2) the Indemnifying Party shall have failed promptly to assume the defense of such Proceeding and to employ counsel reasonably satisfactory to such Indemnified Party in any such Proceeding, or (3) the named parties to any such Proceeding (including any impleaded parties) include both such Indemnified Party and the Indemnifying Party, and counsel to the Indemnified Party shall reasonably believe that a material conflict of interest is likely to exist if the same counsel were to represent such Indemnified Party and the Indemnifying Party (in which case, if such Indemnified Party notifies the Indemnifying Party in writing that it elects to employ separate counsel at the expense of the Indemnifying Party, the Indemnifying Party shall not have the right to assume the defense thereof and the reasonable fees and expenses of no more than one separate counsel shall be at the expense of the Indemnifying Party). Notwithstanding anything in this Section 5, the Indemnifying Party shall not be liable for any settlement of any such Proceeding effected without its written consent, which consent shall not be unreasonably withheld or delayed. No Indemnifying Party shall, without the prior written consent of the Indemnified Party, effect any settlement of any pending Proceeding in respect of which any Indemnified Party is a party, unless such settlement includes an unconditional release of such Indemnified Party from all liability on claims that are the subject matter of such Proceeding.

Subject to the terms of this Agreement, all reasonable and documented fees and expenses of the Indemnified Party (including reasonable and documented fees and expenses to the extent incurred in connection with investigating or preparing to defend such Proceeding in a manner not inconsistent with this Section 5) shall be paid to the Indemnified Party, as incurred, within ten (10) Trading Days of written notice thereof to the Indemnifying Party, provided that the Indemnified Party shall promptly reimburse the Indemnifying Party for that portion of such fees and expenses applicable to such actions for which such Indemnified Party is finally determined by a court of competent jurisdiction (which determination is not subject to appeal or further review) not to be entitled to indemnification hereunder.

(d) Contribution. If the indemnification under Section 5(a) or 5(b) is unavailable to an Indemnified Party or insufficient to hold an Indemnified Party harmless for any Losses, then each Indemnifying Party shall contribute to the amount paid or payable by such Indemnified Party, in such proportion as is appropriate to reflect the relative fault of the Indemnifying Party and Indemnified Party in connection with the actions, statements or omissions that resulted in such Losses as well as any other relevant equitable considerations. The relative fault of such Indemnifying Party and Indemnified Party shall be determined by reference to, among other things, whether any action in question, including any untrue or alleged untrue statement of a material fact or omission or alleged omission of a material fact, has been taken or made by, or relates to information supplied by, such Indemnifying Party or Indemnified Party, and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such action, statement or omission; provided, however, that no Person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) will be entitled to contribution from any Person who was not guilty of such fraudulent misrepresentation. The amount paid or payable by a party as a result of any Losses shall be deemed to include, subject to the limitations set forth in this Agreement, any reasonable attorneys' or other fees or expenses incurred by such party in connection with any Proceeding to the extent such party would have been indemnified for such fees or expenses if the indemnification provided for in this Section 5 was available to such party in accordance with its terms.

The parties hereto agree that it would not be just and equitable if contribution pursuant to this Section 5(d) were determined by pro rata allocation or by any other method of allocation that does not take into account the equitable considerations referred to in the immediately preceding paragraph. In no event shall the contribution obligation of a Holder of Registrable Securities be greater in amount than the dollar amount of the proceeds (net of all expenses paid by such Holder in connection with any claim relating to this Section 5 and the amount of any damages such Holder has otherwise been required to pay by reason of such untrue or alleged untrue statement or omission or alleged omission) received by it upon the sale of the Registrable Securities giving rise to such contribution obligation.

The indemnity and contribution agreements contained in this Section 5(d) are in addition to any liability that the Indemnifying Parties may have to the Indemnified Parties.

6. Miscellaneous.

(a) Remedies. In the event of a breach by the Company or by a Holder of any of their respective obligations under this Agreement, each Holder or the Company, as the case may be, in addition to being entitled to exercise all rights granted by law and under this Agreement, including recovery of damages, shall be entitled to specific performance of its rights under this Agreement. Each of the Company and each Holder agrees that monetary damages would not provide adequate compensation for any losses incurred by reason of a breach by it of any of the provisions of this Agreement and hereby further agrees that, in the event of any action for specific performance in respect of such breach, it shall not assert or shall waive the defense that a remedy at law would be adequate.

(b) No Piggyback on Registrations; Prohibition on Filing Other Registration Statements. Neither the Company nor any of its security holders (other than the Holders in such capacity pursuant hereto) may include securities of the Company in any Registration Statements other than the Registrable Securities. The Company shall not file any other registration statements until all Registrable Securities are registered pursuant to a Registration Statement that is declared effective by the Commission, provided that this Section 6(b) shall not prohibit the Company from filing amendments to registration statements filed prior to the date of this Agreement so long as no new securities are registered on any such existing registration statements, nor preparing and filing with the Commission a registration statements on Form S-8 relating to its equity incentive plans.

(c) Discontinued Disposition. By its acquisition of Registrable Securities, each Holder agrees that, upon receipt of a notice from the Company of the occurrence of any event of the kind described in Section 3(d)(iii) through (v), such Holder will promptly discontinue disposition of such Registrable Securities under a Registration Statement until it is advised in writing (the "**Advice**") by the Company that the use of the applicable Prospectus (as it may have been supplemented or amended) may be resumed. The Company will use its commercially reasonable efforts to ensure that the use of the Prospectus may be resumed as promptly as is practicable.

(d) Amendments and Waivers. The provisions of this Agreement, including the provisions of this sentence, may not be amended, modified or supplemented, and waivers or consents to departures from the provisions hereof may not be given, unless the same shall be in writing and signed by the Company and the Required Holders, provided that, (i) if any amendment, modification or waiver disproportionately and adversely impacts a Holder (or group of Holders), the consent of such disproportionately impacted Holder (or group of Holders) shall be required, including any amendment or modification of Section 5, and (ii) any amendment, modification or waiver of Section 5 shall require the consent of each Holder affected by such amendment, modification or waiver. If a Registration Statement does not register all of the Registrable Securities pursuant to a waiver or amendment done in compliance with the previous sentence, then the number of Registrable Securities to be registered for each Holder shall be reduced pro rata among all Holders and each Holder shall have the right to designate which of its Registrable Securities shall be omitted from such Registration Statement. Notwithstanding the foregoing, a waiver or consent to depart from the provisions hereof with respect to a matter that relates exclusively to the rights of a Holder or some Holders and that does not directly or indirectly affect the rights of other Holders may be given only by such Holder or Holders of all of the Registrable Securities to which such waiver or consent relates; provided, however, that the provisions of this sentence may not be amended, modified, or supplemented except in accordance with the provisions of the first sentence of this Section 6(d). No consideration shall be offered or paid to any Person to amend or consent to a waiver or modification of any provision of this Agreement unless the same consideration also is offered to all of the parties to this Agreement. As used herein, "**Required Holders**" means Holders of 50.1% or more of the then outstanding Registrable Securities (for purposes of clarification, this includes any securities issuable upon conversion or exercise of any Registrable Security).

(e) Notices. Any and all notices or other communications or deliveries required or permitted to be provided hereunder shall be delivered as set forth in the Purchase Agreement.

(f) Successors and Assigns. This Agreement shall inure to the benefit of and be binding upon the successors and permitted assigns of each of the parties and shall inure to the benefit of each Holder. The Company may not assign (except by merger) its rights or obligations hereunder without the prior written consent of the Required Holders. Each Holder may assign their respective rights hereunder in the manner and to the Persons as permitted under Section 9.04 of the Purchase Agreement.

(g) No Inconsistent Agreements. Neither the Company nor any of its subsidiaries has entered, as of the date hereof, nor shall the Company or any of its subsidiaries, on or after the date of this Agreement, enter into any agreement with respect to its securities, that would have the effect of impairing the rights granted to the Holders in this Agreement or otherwise conflicts with the provisions hereof. Neither the Company nor any of its subsidiaries has previously entered into any agreement granting any registration rights with respect to any of its securities to any Person that have not been satisfied in full.

(h) Execution and Counterparts. This Agreement may be executed in two (2) or more counterparts, all of which when taken together shall be considered one and the same agreement and shall become effective when counterparts have been signed by each party and delivered to the other party, it being understood that both parties need not sign the same counterpart. In the event that any signature is delivered by facsimile transmission or by e-mail delivery of a ".pdf" format data file, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or ".pdf" signature page was an original thereof.

(i) Governing Law. All questions concerning the construction, validity, enforcement and interpretation of this Agreement shall be determined in accordance with the provisions of the Purchase Agreement and Section 9.07 of the Purchase Agreement is hereby incorporated herein *mutatis mutandi*.

(j) Cumulative Remedies. The remedies provided herein are cumulative and not exclusive of any other remedies provided by law.

(k) Severability. If any term, provision, covenant or restriction of this Agreement is held by a court of competent jurisdiction to be invalid, illegal, void or unenforceable, the remainder of the terms, provisions, covenants and restrictions set forth herein shall remain in full force and effect and shall in no way be affected, impaired or invalidated, and the parties hereto shall use their commercially reasonable efforts to find and employ an alternative means to achieve the same or substantially the same result as that contemplated by such term, provision, covenant or restriction. It is hereby stipulated and declared to be the intention of the parties that they would have executed the remaining terms, provisions, covenants and restrictions without including any of such that may be hereafter declared invalid, illegal, void or unenforceable.

(l) Headings. The headings in this Agreement are for convenience only, do not constitute a part of the Agreement and shall not be deemed to limit or affect any of the provisions hereof.

(m) Independent Nature of Holders' Obligations and Rights. The obligations of each Holder hereunder are several and not joint with the obligations of any other Holder hereunder, and no Holder shall be responsible in any way for the performance of the obligations of any other Holder hereunder. Nothing contained herein or in any other agreement or document delivered at any closing, and no action taken by any Holder pursuant hereto or thereto, shall be deemed to constitute the Holders as a partnership, an association, a joint venture or any other kind of group or entity, or create a presumption that the Holders are in any way acting in concert or as a group or entity with respect to such obligations or the transactions contemplated by this Agreement or any other matters, and the Company acknowledges that the Holders are not acting in concert or as a group, and the Company shall not assert any such claim, with respect to such obligations or transactions. Each Holder shall be entitled to protect and enforce its rights, including without limitation the rights arising out of this Agreement, and it shall not be necessary for any other Holder to be joined as an additional party in any proceeding for such purpose. The use of a single agreement with respect to the obligations of the Company contained was solely in the control of the Company, not the action or decision of any Holder, and was done solely for the convenience of the Company and not because it was required or requested to do so by any Holder. It is expressly understood and agreed that each provision contained in this Agreement is between the Company and a Holder, solely, and not between the Company and the Holders collectively and not between and among Holders.

****

(Signature Pages Follow)

IN WITNESS WHEREOF, the parties have executed this Registration Rights Agreement as of the date first written above.

ORUKA THERAPEUTICS, INC.

By: _____
Name:
Title:

[*Signature Page to Registration Rights Agreement*]

ARCA BIOPHARMA, INC.

By: _____
Name:
Title:

[SIGNATURE PAGE OF HOLDERS FOLLOWS]

[*Signature Page to Registration Rights Agreement*]

IN WITNESS WHEREOF, the parties have executed this Registration Rights Agreement as of the date first written above.

[●]

By: _____
Name:
Title:

[*Signature Page to Registration Rights Agreement*]

Annex A

Plan of Distribution

Annex B

SELLING STOCKHOLDERS

Annex Cs

Selling Stockholder Notice and Questionnaire

Annex D

HOLDER REPRESENTATION LETTER

Exhibit 31.1

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

I, Lawrence Klein, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Oruka Therapeutics, Inc.;

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2024

By: /s/ Lawrence Klein

Lawrence Klein
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Arjun Agarwal, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Oruka Therapeutics, Inc.;

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2024

By: /s/ Arjun Agarwal

Arjun Agarwal
Senior Vice President, Finance
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Oruka Therapeutics, Inc. (the "Company") for the quarterly period ending September 30, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: November 13, 2024

By: /s/ Lawrence Klein

Lawrence Klein
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 13, 2024

By: /s/ Arjun Agarwal

Arjun Agarwal
Senior Vice President, Finance
(Principal Financial Officer and Principal Accounting Officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. §1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Note: A signed original of this written statement required by §906 has been provided to Oruka Therapeutics, Inc. and will be retained by Oruka Therapeutics, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.