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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2025

OR

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

FOR THE TRANSITION PERIOD FROM TO

Commission File Number 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)**

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

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

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

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

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

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

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

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant as of June 30, 2025, was approximately $371.5 million based on the closing price of the Registrant's shares of common stock on The Nasdaq Capital Market on such date.

The number of shares of the Registrant's common stock outstanding as of February 28, 2026 was 49,542,691.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or Annual Report, contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These forward-looking statements reflect the current views of Oruka Therapeutics, Inc. ("Oruka", the "Company", "we", or "us") with respect to future events and are based on assumptions and subject to known and unknown risks and uncertainties and other factors that may cause our actual results, performance, time frames or achievements to be materially different from any future results, performance, time frames or achievements expressed or implied by the forward-looking statements. Factors that might cause such a difference are disclosed in the section titled "Risk Factors" in this Annual Report. We caution readers that any forward-looking statement is not a guarantee of future performance and that actual results could differ materially from those contained in the forward-looking statement. These statements are based on current expectations of future events. You should evaluate all forward-looking statements made in this Annual Report in the context of these risks and uncertainties. We caution you that the risks, uncertainties and other factors referred to in this Annual Report may not contain all of the risks, uncertainties and other factors that may affect our future results and operations. Moreover, we operate in a very competitive and rapidly changing environment, and new risks and uncertainties emerge from time to time.

All statements, other than statements of historical facts contained in this Annual Report, including, without limitation, statements regarding: our future results of operations and financial position, business strategy, the length of time that we believe our existing cash resources will fund our operations, our market size, our competition, our potential growth opportunities, our clinical development activities and timeline, the efficacy and safety profile of our product candidates, the potential therapeutic benefits and economic value of our product candidates, the timing and results of preclinical studies and clinical trials, the expected impact of macroeconomic conditions, including inflation, increasing interest rates and volatile market conditions, current or potential bank failures, as well as global events, including military conflicts and geopolitical tensions on our operations, and the receipt and timing of potential regulatory designations, approvals and commercialization of product candidates, are forward-looking statements. The words "believe," "may," "will," "potentially," "estimate," "continue," "anticipate," "predict," "target," "intend," "could," "would," "should," "project," "plan," "expect," and similar expressions that convey uncertainty of future events or outcomes are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements are based on information available to us as of the date of this Annual Report and are subject to a number of risks, uncertainties and assumptions, including those described in Item 1A, "Risk Factors" and elsewhere in this Annual Report. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties, and assumptions, the forward-looking events and circumstances discussed in this Annual Report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. While we believe that such information provides a reasonable basis for these statements, such information may be limited or incomplete. Our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely on these statements.

All subsequent written or oral forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. We do not undertake any obligation to release publicly any revisions to these forward-looking statements to reflect events or circumstances after the date of this Annual Report or to reflect the occurrence of unanticipated events, except as may be required under applicable U.S. securities laws. You should read this Annual Report with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect. If we do update one or more forward-looking statements, no inference should be drawn that we will make additional updates with respect to those or other forward-looking statements.

Unless the context indicates otherwise, as used in this Annual Report, the terms "Oruka," "ARCA biopharma, Inc.," "the Company," "we," "us," and "our" refer to Oruka Therapeutics, Inc., a Delaware corporation, and its consolidated subsidiary taken as a whole. "Oruka" and all product candidate names are our common law trademarks. This Annual Report contains additional trade names, trademarks and service marks of other companies, which are the property of their respective owners. We do not intend our use or display of other companies' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies.

PART I

Item 1. Business.

Acquisition of Pre-Merger Oruka

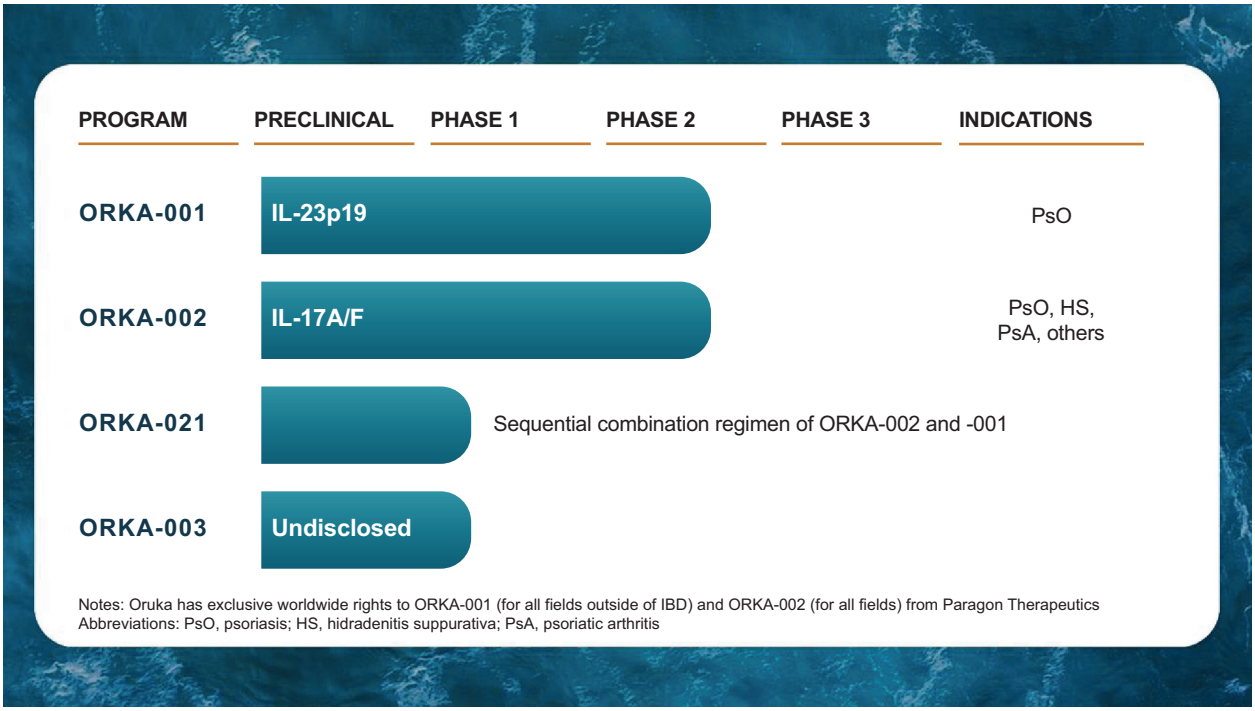
On August 29, 2024 (the "Merger Closing"), we completed our acquisition (the "Merger") of Oruka Therapeutics, Inc. ("Pre-Merger Oruka") pursuant to an Agreement and Plan of Merger and Reorganization, dated as of April 3, 2024 (the "Merger Agreement"). Following the transactions contemplated by the Merger Agreement, Pre-Merger Oruka merged with and into Atlas Merger Sub Corp., a wholly owned subsidiary of ARCA biopharma, Inc. ("ARCA") and following that, Pre-Merger Oruka then merged with and into Atlas Merger Sub II, LLC ("Second Merger Sub"), with Second Merger Sub being the surviving entity. Second Merger Sub changed its corporate name to "Oruka Therapeutics Operating Company, LLC". Pre-Merger Oruka was a pre-clinical stage biotechnology company that was incorporated on February 6, 2024 under the direction of Peter Harwin, a Founding Partner at Fairmount Funds Management LLC ("Fairmount"), for the purposes of holding rights to certain intellectual property being developed by Paragon Therapeutics, Inc. ("Paragon"). On August 29, 2024, we changed our name from "ARCA biopharma, Inc." ("ARCA") to "Oruka Therapeutics, Inc." and our Nasdaq ticker symbol from "ABIO" to "ORKA".

Company Overview

We are a clinical-stage biopharmaceutical 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 most 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 reducing 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 ("TRMs").

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, hidradenitis suppurativa ("HS"), psoriatic arthritis ("PsA"), and other conditions. The product candidates in 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.

Our Portfolio and Development Plans



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 clinical 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 fragment crystallizable ("Fc") domain to modify the pH-dependent binding to the neonatal Fc receptor ("FcRn"). As a result, it has a pharmacokinetic profile designed to support a subcutaneous ("SQ") injection as infrequently as once or twice per 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 anticipated characteristics of ORKA-001 enhance its potential to deliver these disease-modifying benefits.

We initiated a Phase 1 trial of ORKA-001 in the fourth quarter of 2024 and in September 2025, we announced the interim results at the European Academy of Dermatology and Venereology (EADV) Congress. The data showed that ORKA-001 has a human half-life of approximately 100 days. Single doses of ORKA-001 demonstrated complete and sustained inhibition of STAT3 signaling, a downstream marker of IL-23 activity, in an ex vivo assay through 24 weeks. In addition, ORKA-001 was well tolerated at all dose levels, with a favorable safety profile consistent with the anti-IL-23 class.

In the third quarter of 2025, we commenced dosing in a Phase 2a clinical trial of ORKA-001 in patients with moderate-to-severe PsO (also known as "EVERLAST-A"). We expect to share Week 16 data for all patients in the second quarter of 2026. In addition, we plan to share longer-term data, including Week 28 for all patients and 52-week follow-up for a portion of the cohort in the second half of 2026. EVERLAST-A enrolled 84 patients randomized 3:1 to receive 600 mg of ORKA-001 at Weeks 0 and 4 or matching placebo. The primary endpoint is PASI 100, a 100% reduction from baseline in Psoriasis Area and Severity Index ("PASI"), at Week 16. At Week 28, patients who have

achieved PASI 100 will be randomized 2:1 to an arm where either (1) they do not receive another dose until disease recurrence (to evaluate the possibility of both yearly dosing and extended off-treatment remissions) or (2) they receive 300 mg ORKA-001 every six months. Patients who have not achieved PASI 100 will receive a 300 mg dose every six months.

Additionally, the first patients were dosed in EVERLAST-B in December 2025. EVERLAST-B is designed to enroll approximately 160 patients into a dose-ranging Phase 2b trial of ORKA-001 in patients with moderate-to-severe PsO and will evaluate three dose levels of ORKA-001: 37.5 mg at Week 0, 300 mg at Weeks 0 and 4, and 600 mg at Weeks 0 and 4, versus placebo. The primary endpoint is PASI 100 at Week 16. At Week 28, patients who have achieved PASI 100 will be re-randomized 1:1 to either a 600 mg dose once-yearly or matching placebo. Patients who have not achieved PASI 100 at Week 28 will receive a 300 mg dose every six months. Building on EVERLAST-A, this design will further test the potential for ORKA-001 to achieve yearly dosing, higher efficacy and extended off-treatment remissions. Data from EVERLAST-B is anticipated in 2027.

Based on recent precedent in PsO, we anticipate that the overall development program, from first-in-human studies through biologics license application ("BLA") submission could take as little as six to seven years, based on averages observed for recently approved medicines. However, we have no control over the duration of the United States Food and Drug Administration ("FDA") review process, and the actual timeline may vary.

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 HS and axial spondyloarthritis ("axSpA"). 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.

In January 2026, we announced interim findings from the Phase 1 trial of ORKA-002 in healthy volunteers. The results showed that ORKA-002 has a half-life of approximately 75-80 days, which supports the potential for twice-yearly maintenance dosing in PsO and quarterly maintenance dosing in HS. Single doses of ORKA-002 demonstrated potent and sustained inhibition of IL-17 signaling in an ex vivo assay through 24 weeks. ORKA-002 was well tolerated at all dose levels, with a favorable safety profile consistent with the anti-IL-17 class. The trial remains blinded, and as of January 6, 2026, which was the data cutoff date, all subjects remained on trial.

Based on these Phase 1 results, we initiated ORCA-SURGE, a Phase 2 trial of ORKA-002 in patients with moderate-to-severe PsO, in February 2026. ORCA-SURGE is designed to enroll approximately 160 patients randomized 1:1:1:1 to receive 40 mg, 160 mg or 320 mg of ORKA-002 at Weeks 0 and 4, or matching placebo. The primary endpoint is PASI 100 at Week 16. Maintenance dosing will evaluate the potential for twice-yearly dosing with ORKA-002. Data from ORCA-SURGE is anticipated in 2027. Moreover, we also expect to initiate a Phase 2 trial of ORKA-002 in patients with HS in the second 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. Furthermore, we plan to pursue a sequential combination regimen of ORKA-002 followed by ORKA-001, called ORKA-021. ORKA-021 has the potential to combine the rapid response of an IL-17 inhibitor with the superior maintenance profile of an IL-23 inhibitor in a single regimen. We believe that 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 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.

Our Team, Investors, and Paragon Collaboration

We are led by a management team with significant experience in developing novel treatments for patients at biopharmaceutical companies such as CRISPR Therapeutics, Celgene, Novartis, CymaBay Therapeutics and Protagonist Therapeutics. Together, our team has a proven track record of building successful biotech organizations in high-growth environments.

Pre-Merger Oruka was founded in February 2024 by leading healthcare investor Fairmount. Fairmount founded Paragon in 2021 to conduct biologics discovery and optimization, including acting as the firm's discovery engine for biologics that potentially overcome limitations of existing therapies. We have entered into license agreements with Paragon pursuant to which Paragon granted us a royalty-bearing, world-wide, exclusive license to develop, manufacture, commercialize or otherwise exploit certain antibodies and products targeting IL-23 outside of the field of inflammatory bowel disease for ORKA-001 and for ORKA-002, certain antibodies and products targeting IL-17A/F in all fields.

Our Strategy

To achieve our goal of developing leading therapeutic antibodies for patients with inflammatory skin diseases, we are applying antibody engineering to validated modes of action. We believe this approach will enable us to improve meaningfully upon the efficacy and convenience of standard-of-care medicines while significantly reducing technical and biological risk. The key elements of our strategy include:

- ***Employ advanced antibody engineering to build biologics that could significantly improve upon existing therapies:*** We and our collaborators at Paragon have optimized a variety of parameters using a suite of antibody technologies to develop product candidates with the potential to improve upon existing therapies. These parameters include extending half-life to increase exposure and reduce dosing frequency, enhancing affinity and specificity to maximize potency and safety, and optimizing developability to ensure consistency and enable convenient, high-dose formulations. Together, we believe these features have the potential to translate into more efficacious and convenient medicines for patients.

- ***Target validated mechanisms of action:*** Our initial targets, IL-23p19 and IL-17A/F, have established efficacy and safety for the treatment of PsO, PsA, and other indications. The FDA has approved five biologics in the IL-23 class, including four targeting IL-23p19, and four biologics in the IL-17 class, including one targeting IL-17A/F. While these therapies have advanced the standard of care in PsO and PsA, they have not addressed these diseases completely, and a significant fraction of patients do not achieve complete skin clearance. By applying our advanced antibody engineering to these validated targets, we believe we can maximize our chances of developing superior medicines for patients. In addition, the reduced technical and biological risk of these validated mechanisms may allow us to progress our programs more efficiently and rapidly.

- ***Leverage insights from earlier entrants to optimize our approach:*** We benefit from a large body of clinical evidence generated by prior therapies targeting IL-23 and IL-17. We continue to extract and apply learnings from this precedent to our programs, including in development candidate selection, clinical trial design, dosing regimens, formulations and presentations, regulatory pathway, and indication prioritization. For instance, based on correlations between affinity and efficacy, we have designed ORKA-001 and ORKA-002 to bind to similar epitopes and at similar or greater affinities as the leading antibodies in each class: risankizumab and bimekizumab, respectively, with the aim of maximizing efficacy. Also, by understanding the exposure-response relationships for efficacy and safety for other therapies, we plan to select dose levels and regimens that could maximize efficacy and maintenance of response while maintaining safety.

- ***Pursue opportunities with strong prospects of yielding meaningful new medicines as a "base case" and the potential to shift the treatment paradigm entirely as an "upside case":*** Our strategy seeks to maximize the potential for our programs to reach a base case product profile that could meaningfully advance the standard of care — for instance, for ORKA-001, SQ dosing one or twice per year with equal or greater efficacy compared to today's standard of care. At the same time, we aim to deliver an upside case that dramatically improves outcomes for patients — for instance, significantly increasing rates of complete skin clearance via higher antibody exposures or offering patients durable remissions free from therapy by introducing patient-specific dosing intervals.

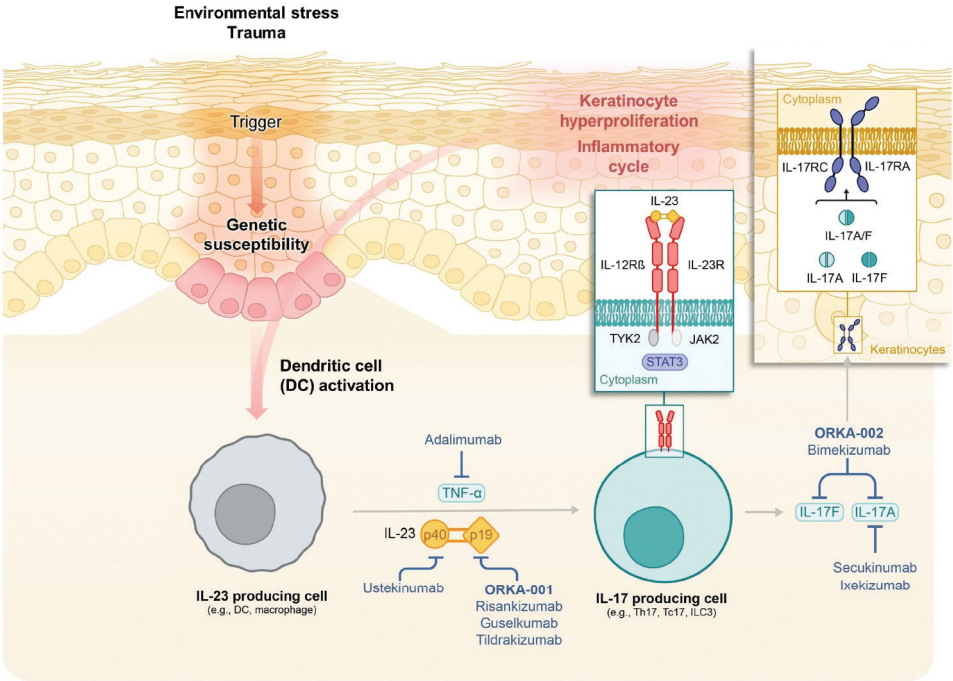
- ***Build a preeminent biopharmaceutical company focused on chronic skin disease and other I&I indications:*** We are assembling a team of exceptional people and helping them reach their full potential and flourish so that together we can bring forward meaningful new medicines for patients.

We believe that pursuing the focused strategy outlined above will help us to succeed in our mission of offering patients living with PsO, PsA, and other dermatologic and inflammatory diseases the greatest possible freedom from their condition.

Targeting IL-23 and IL-17 to Treat Multiple I&I Indications

Our programs benefit from significant advances in the understanding of the biology of I&I diseases over the past four decades. ORKA-001 and ORKA-002 are designed to target two key cytokines that play a related role in multiple indications. IL-23 is an upstream regulator of Th17 cells, a pro-inflammatory subset of T helper cells characterized by their production of IL-17. IL-23 has a critical role in maintaining Th17 cells in the tissue as well as activating these cells to secrete IL-17, which acts downstream to trigger inflammation and other disease symptoms. Th17 cells are involved in PsO, HS, PsA, axSpA, and many other diseases. They play a particularly central role in PsO and PsA. The diagram below depicting the immunopathogenesis of PsO provides an example of how Th17 cells can mediate disease and how blocking IL-23 or IL-17 can break the inflammatory cycle that drives disease.

Immunopathogenesis of PsO and the role of IL-23 and IL-17



Adapted from 2022 Song (Immune Network) & 2014 Bartlett (Nature Reviews Drug Discovery)

PsO develops when environmental triggers and a genetic predisposition combine to cause activation of an inflammatory cycle in the skin that leads to the formation of plaques and other disease manifestations. This process begins with the aberrant activation of the dendritic cells ("DCs"), specifically those producing IL-23 and other cytokines like IL-1β, IL-21, TNF-α, and IL-12. These cytokines induce the differentiation of Th17 cells, as well as

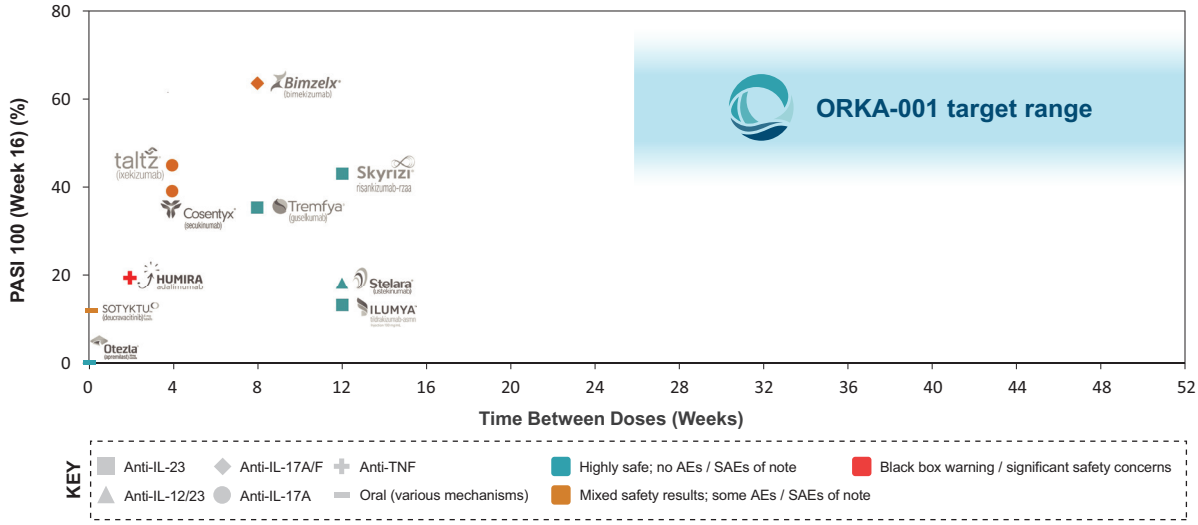
other cell types, such as T helper type 1 ("Th1") cells that produce IFNγ and TNF-α and T helper type 22 ("Th22") cells that produce IL-22. IL-23 plays a key role in the differentiation and activation of Th17 cells to secrete IL-17, as well as Th22 cells to produce IL-22. IL-17 and these other cytokines induce keratinocyte hyperproliferation leading to plaque formation and a feedforward inflammatory response, with changes in gene expression in keratinocytes, the production of antimicrobial peptides, and neutrophil recruitment driving further inflammation. While many cytokines and cell types contribute to the pathogenesis of PsO, the IL-23/IL-17 axis plays an important role, as supported by the success of therapies targeting this axis.

While the successful treatment of PsO — for instance, with mAbs targeting IL-23 or IL-17 — can result in lesional skin returning to an apparently normal state, disease tends to recur at previously affected sites following cessation of therapy, suggesting a mechanism of "immunological memory" that predisposes individuals to recurrence in the same locations. Evidence suggests that pathogenic TRMs play a critical role in this memory. TRMs may arise from the Th17 cells and other cells that drove disease in the first place and remain in their resident tissue, in this case the epidermis and dermis, for long periods of time. Upon a disease trigger, these TRMs can actively produce proinflammatory cytokines, causing disease recurrence. IL-23 appears to play an important role in maintaining and potentiating TRMs, as indicated by the depletion of TRMs following treatment with an IL-23 inhibitor but not an IL-17 inhibitor, which may explain the longer remissions observed with IL-23 inhibitors following withdrawal of therapy. This type of data has raised the prospect that efficient IL-23 blockade could modify the disease biology of PsO, possibly leading to durable remissions.

The scientific discoveries that refined our understanding of the immunopathogenesis of PsO have led to waves of therapeutic advances, ultimately leading to today's standard of care. Before the 1980s, PsO was not even thought of as an immunologic disease, but rather a disease of keratinocyte dysfunction, leading to treatments such as phototherapy, methotrexate, and retinoids. The discovery in the 1980s that PsO results from immune dysfunction led to the use of broad immunosuppressants like cyclosporine. From 1990 to 2008, it was believed that Th1 cells were the predominant mediators of the disease, which led to the use of biologics targeting TNF-α such as Enbrel (etanercept) and Humira (adalimumab). Finally, the revelation that PsO is driven principally by Th17 cells resulted in the development of the primary therapies used today, which target IL-23 and IL-17. This increasingly refined understanding of the disease has narrowed the standard of care from broad immunosuppressive agents (such as cyclosporine) to more specific immunomodulators (TNF-α inhibitors) to precise biologic therapies targeting the key cytokines involved in disease pathology (IL-23 and IL-17 inhibitors), with each new therapeutic class raising the bar on both safety and efficacy.

Biologic therapies, especially mAbs, are now mainstays in the treatment of a wide variety of I&I diseases, including PsO and PsA. Therapies that have improved upon efficacy and/or reduced dosing frequency have achieved the most commercial success, even when launched many years after other biologics. Enbrel was first approved for PsO in 2004 with a weekly maintenance dosing schedule. Four years later, Humira was approved for PsO with an every-other-week (Q2W) dosing schedule. Stelara (ustekinumab) was approved a year later with similar Phase 3 data to Humira, but with a significantly improved dosing schedule of every twelve weeks (Q12W). Several drugs for PsO have been approved since 2009 that demonstrated higher efficacy in their pivotal studies compared to Stelara, but with more burdensome dosing schedules, including Tremfya (guselkumab), which has a dosing schedule of every eight weeks (Q8W), and Cosentyx (secukinumab) and Taltz (ixekizumab), which have dosing schedules of every four weeks (Q4W). While these therapies have all become generally successful products, the most commercially successful drug in the PsO market today is Skyrizi (risankizumab), which combines Stelara's Q12W dosing schedule with improvements in efficacy, as evidenced by a higher PASI score of PASI 90 and PASI 100 rates (i.e., a 90% improvement in PASI score and a 100% improvement in PASI score (complete clearance), respectively) in clinical trials. In addition, Bimzelx (bimekizumab), approved by the FDA in 2023, has shown evidence of efficacy that exceeds even Skyrizi, though with a less convenient Q8W dosing schedule. Although many biologics have entered the PsO market over the past two decades, new entrants have had significant commercial success when they have improved upon efficacy and/or dosing frequency, and room remains to improve in both areas to set a new standard for the treatment of PsO.

Biologics have raised the bar on the standard of care in PsO, but leave room for improvement



The biology driving PsO and PsA is well understood today, and the standard of care has progressed dramatically. We believe that it is unlikely that a novel mechanism will emerge that is as safe and efficacious as targeting the IL-23/IL-17 axis. Therefore, we believe that innovation now should be focused on optimizing the product profile that can be offered to patients. While much effort is being directed toward daily oral formats to inhibit this axis, oral medicines have yet to match the efficacy of biologics. We believe that a better biologic with a longer dosing interval and the potential for improved efficacy will present a more attractive product profile for most patients.

Overview of Psoriasis (PsO)

PsO is a chronic autoimmune skin disorder that affects an estimated 125 million people worldwide with steadily increasing prevalence, estimated to be around 2 – 3% of the population currently, according to the International Federation of Psoriasis Associations ("IFPA"). It is the largest pharmaceutical market within dermatology, with annual global sales of approximately $28 billion in 2024, which is estimated to grow to approximately $40 billion by 2032. The most common form of PsO is plaque psoriasis. Patients with chronic plaque psoriasis have well-demarcated, erythematous plaques with overlying, coarse, silvery-scaled patches. These plaques can occur anywhere on the body, though are typically found on the scalp, extensor areas of the knees and elbows, and gluteal cleft. Involvement of the palms, soles, or nails, and intertriginous areas, including the genitals, can also occur and can be particularly difficult to treat. Between one-quarter and one-half of PsO patients have moderate disease, defined as having 3% to 10% of the body surface area ("BSA") involved, or severe disease, defined as having more than 10% BSA involvement. The chronic inflammation in PsO is associated with multiple comorbidities, including PsA, obesity, metabolic syndrome, hypertension, diabetes, and atherosclerotic cardiovascular disease.

As discussed earlier, PsO is a complex immune-mediated disease driven primarily by Th17 cells and the cytokines IL-23 and IL-17. The interplay of environmental and behavioral risk factors and genetics is believed to trigger PsO. Multiple lines of evidence support a genetic component to the disease, including the observation that approximately 40% of patients with PsO and PsA have a family history of the disease and the identification of multiple susceptibility loci, many containing genes related to the regulation of the immune system, in genome-wide association studies.

Current PsO Treatments and Limitations

While patients with mild PsO typically rely on topical corticosteroids or oral therapies like Otezla (apremilast), these agents often do not provide an adequate response for patients with moderate-to-severe PsO. As a result, the American Academy of Dermatology-National Psoriasis Foundation recommends biologics as first-line therapy for moderate-to-severe PsO.

Several classes of biologic therapies have been approved for PsO over the past 20 years, resulting in progressively more complete symptom relief. Efficacy in PsO is typically measured via the PASI scoring system. The first biologics approved for PsO were tumor necrosis alpha ("TNF-α") inhibitors such as Enbrel (etanercept), Humira (adalimumab), and Remicade (infliximab), which achieved a PASI score of PASI 90 at 16 weeks in around 25 – 50% of patients and a PASI score of PASI 100 in around 5 – 20% of patients. Stelara (ustekinumab), which targets the p40 subunit of IL-23 that is shared with IL-12, was approved next and achieved efficacy on par with Humira. IL-17 inhibitors Cosentyx (secukinumab), Taltz (ixekizumab), and Siliq (brodalumab) followed and achieved responses of PASI 90 in around 70% of patients and PASI 100 in around 40% of patients with some risk of certain side effects such as oral candidiasis. Most recently, IL-23p19 inhibitors such as Ilumya (tildrakizumab), Tremfya (guselkumab), and Skyrizi (risankizumab) have achieved responses of PASI 90 in around 70 – 80% of patients and PASI 100 in around 30 – 50% of patients with highly tolerable profiles. Finally, IL-17A/F inhibitors such as Bimzelx (bimekizumab) have recently shown even higher response rates than IL-23 inhibitors, but with slightly less tolerable profiles.

Treatment expectations in PsO have evolved progressively with this continued innovation. A 75% improvement in PASI score was previously thought to be an adequate depth of response, and weekly SQ dosing was viewed as acceptable. With each subsequent generation of innovation, patient and caregiver expectations have advanced. Today, Skyrizi (risankizumab) is widely viewed as the leader in PsO biologic therapy. In Phase 3 clinical trials, 43% and 58% of patients achieved PASI 100 at 16 and 52 weeks, respectively, with SQ maintenance dosing every three months. Most recently, Bimzelx (bimekizumab) has shown evidence of efficacy that exceeds even Skyrizi, achieving a 64% PASI 100 rate at 16 weeks in Phase 3 trials. However, the increased efficacy comes with a less convenient Q8W dosing schedule and an increased risk of certain side effects, most notably oral candidiasis. While agents like Skyrizi and Bimzelx reflect the remarkable advancement in PsO treatment, there remains significant unmet need. Approximately half of moderate-to-severe PsO patients do not achieve full skin clarity, and while early signs are present, the promise of disease modifying therapy remains unrealized. In addition, a continued desire for more convenient dosing options has driven significant interest in orally delivered medicines targeting these same pathways. However, oral therapies have yet to match the efficacy and safety profile of biologics. We believe that ORKA-001 and ORKA-002 could represent the next step in biologic innovation in PsO, with the potential for higher rates of complete skin clearance, more durable remissions, and markedly more convenient dosing regimens.

Overview of Hidradenitis Suppurativa ("HS")

HS is a chronic inflammatory skin disease characterized by deep-seated nodules and abscesses, draining sinus tracts, and fibrotic scarring that most commonly occur in intertriginous areas, such as the axillae and groin. Due to the associated pain, sensitive anatomical locations, drainage, odor, scarring, and recurrent disease flares, HS can have a substantial negative psychosocial impact across many areas of life, including interpersonal relationships, education, and employment.

HS is believed to be underdiagnosed and may have a prevalence exceeding 1% worldwide. Significant delays between symptom onset and diagnosis are common; an average delay of 7 – 10 years has been reported, with some patients waiting more than 20 years for diagnosis. This compares to an average time to diagnosis of approximately 1.6 years for psoriasis. Delayed diagnosis has been associated with worsening disease severity, progression, and an increased burden of comorbidities, potentially due to delays in receiving appropriate anti-inflammatory treatment.

Current HS Treatments and Limitations

The overall treatment goals for HS include alleviating lesion-related symptoms (e.g., pain), reducing the frequency and severity of disease flares, limiting the formation of new inflammatory lesions, and preventing disease progression and associated comorbidities. Treatment varies depending on disease severity and may include topical and systemic antibiotics, hormone therapy, immunomodulators, and surgical interventions. Humira (adalimumab) was the only FDA-approved medication for the treatment of moderate-to-severe HS from its approval in 2015 until the approval of Cosentyx (secukinumab) in October 2023 and Bimzelx (bimekizumab) in November 2024.

The hidradenitis suppurativa clinical response (HiSCR) outcome measure is currently considered the standard primary endpoint for the assessment of new pharmacologic interventions in HS clinical trials. HiSCR50, HiSCR75, and HiSCR90 are defined as at least a 50%, 75%, or 90% reduction from baseline in the total abscess and inflammatory nodule count, with no increase from baseline in abscess or draining tunnel count. A recent network meta-analysis

comparing approved biologics for moderate-to-severe HS found that Bimzelx (bimekizumab) ranked highest across HiSCR efficacy endpoints. In Phase 3 studies, Bimzelx (bimekizumab) demonstrated placebo-adjusted HiSCR50/75 rates of 18 – 20%, and 15 – 20%, respectively, at Week 16 with Q2W dosing.

In addition to currently approved therapies, multiple biologic and oral agents targeting a range of inflammatory pathways are advancing through clinical development for HS. These investigational therapies span diverse mechanisms of action and several have demonstrated encouraging efficacy signals in Phase 2 clinical trials. However, currently approved therapies and late-stage investigational agents are typically administered on weekly, bi-weekly, or monthly dosing schedules, and a substantial proportion of patients continue to experience inadequate or incomplete disease control. These factors underscore the ongoing unmet need for more effective, durable, and more conveniently administered treatment options.

Overview of Psoriatic Arthritis (PsA)

PsA is a chronic inflammatory condition that affects both the skin and joints, and often coexists with PsO. Around a quarter to a third of patients with moderate-to-severe PsO also have PsA. Most individuals develop PsO before being diagnosed with PsA, with a median gap of seven to eight years between the diagnosis of skin and joint disease, though in up to 30% of patients with PsA, joint symptoms appear before or simultaneously with skin manifestations. Patients with PsA present with joint pain, stiffness, and swelling affecting the peripheral joints, axial skeleton, or both. Enthesitis, dactylitis, nail lesions, fatigue, and ocular inflammation all occur commonly. PsA can lead to irreversible joint damage, including bony fusion across a joint (ankylosis). The pathogenesis of PsA is likely to be closely related to the mechanisms that underlie PsO. Like PsO, the exact cause of PsA remains unknown, but environmental triggers, including infection and trauma, and genetic factors play a role.

Current PsA Treatments and Limitations

Effective treatment of PsA requires a coordinated approach to address the unique combination of disease manifestations each patient has, which can include peripheral and axial arthritis, enthesitis, dactylitis, and skin and nail involvement. Many patients with milder disease symptoms will start with nonsteroidal anti-inflammatory drugs ("NSAIDs") and/or local treatments to address specific disease manifestations. However, those with more moderate or severe disease and/or multidomain involvement will typically receive a biologic therapy targeting TNF-α or IL-17, or less commonly an oral Janus kinase ("JAK") inhibitor. Comorbid conditions can also influence treatment selection. For example, an IL-17 inhibitor would be preferred for a patient with significant skin involvement, but not for patients with IBD or ocular symptoms, where a TNF-α inhibitor would be preferred. The most common endpoint used to measure the efficacy of TNF-α or IL-17 inhibitors in PsA is ACR response, or the proportion of patients achieving a specified percent improvement in American College of Rheumatology ("ACR") score, which measures peripheral joint disease. Approved TNF-α inhibitors, including Humira (adalimumab) and Cimzia (certolizumab), achieved a placebo-adjusted ACR50 response of around 30 – 35% at 24 weeks with Q2W dosing. Approved IL-17 inhibitors, including Cosentyx (secukinumab) and Taltz (ixekizumab), achieved a slightly lower placebo-adjusted ACR50 response of around 25 – 30% at 24 weeks, but with more convenient Q4W dosing. Bimzelx (bimekizumab), which was recently approved in the United States for PsA, achieved a placebo-adjusted ACR50 response of approximately 35% at 16 weeks with Q4W dosing. A significant fraction of patients with PsA still do not achieve a satisfactory response with available therapies, and even the most convenient regimens require monthly SQ dosing.

Overview of additional opportunities

In addition to PsO, HS, and PsA, inhibition of IL-23 or IL-17 has demonstrated efficacy in a number of additional I&I indications, such as axSpA.

axSpA is a chronic inflammatory disease that primarily affects the spine and sacroiliac joints that comprise the axial skeleton. The disease causes severe pain, stiffness, and fatigue, and can have additional clinical manifestations like uveitis, enthesitis, peripheral arthritis, and PsO. Patients with axSpA may develop further structural damage in their spine, which can lead to the fusion of vertebra (spinal ankylosis), which has a massive negative impact on mobility, physical function, and quality of life. The overall prevalence of axSpA is estimated to be around 1% in the United States. Treatment of axSpA starts with physical therapy and NSAIDs. If patients do not have an adequate response

to NSAIDs, a TNF-α inhibitor is typically used, followed by an IL-17 inhibitor, such as Cosentyx (secukinumab), Taltz (ixekizumab), or Bimzelx (bimekizumab), or less frequently a JAK inhibitor. Patients often need to cycle through therapies over time due to inadequate responses or loss of response.

Our Solution: Half-Life Extension and Antibody Engineering Technologies

Our antibody engineering campaigns are designed to optimize multiple attributes in parallel: binding affinity, potency in a variety of assays, developability, and consistently extended serum half-life in non-human primates ("NHPs"). Half-life extension is possible by modifying the pH-dependent binding affinity of the antibody Fc domain for FcRn. A primary mechanism of elimination of antibodies from the serum is through pinocytosis and degradation in the lysosomes of cells. Throughout this process, antibodies can be recycled back into the serum by binding to FcRn while they are in endosomes. The interior of the endosome is acidic, and therefore the efficiency of this recycling process depends on the ability of the antibody Fc domain to bind to FcRn at low pH. If this low pH binding is efficient enough, antibody recycling can be favored over degradation, potentially resulting in a much longer serum half-life.

Antibody engineers have discovered methods of modifying the Fc domain to optimize the efficiency of recycling via FcRn binding. Several engineering strategies have been identified over the past two decades, with the so-called "YTE" mutations (M252Y/S254T/T256E) and "LS" mutations (M428L/N434S) being the most frequently used. Importantly, while these strategies have been known for some time, it was only relatively recently that enough clinical precedent was established to provide confidence in how these mutations perform in humans. Three products incorporating YTE or LS modifications are currently approved by the FDA, Beyfortus (nirsevimab), Exdensur (depemokimab), and Ultomiris (ravulizumab), and several more candidates are in clinical trials. Based on clinical data in humans, antibodies with YTE mutations typically have a half-life that is two to four times longer than wildtype antibodies.

ORKA-001

Summary

ORKA-001 is a high affinity, extended half-life mAb designed to target the p19 subunit of IL-23. Based on both preclinical and clinical data generated to date, we believe ORKA-001 has the potential to become the leading IL-23 inhibitor and achieve an optimal product profile in PsO consisting of the following:

- ***One to two maintenance doses per year.*** Standard-of-care therapies targeting IL-23 require maintenance dosing every eight to twelve weeks. We engineered the Fc portion of ORKA-001 to include YTE mutations to increase the half-life of ORKA-001 in circulation, which may enable dosing every six to twelve months — a dosing interval made feasible by half-life extension technology. In clinical studies, ORKA-001 demonstrated a human half-life of approximately 100 days. Based on pharmacokinetic modeling, we anticipate this half-life to enable subcutaneous dosing every six to twelve months while maintaining high antibody exposures.

- ***Higher PASI 100.*** ORKA-001 benefits from the robust validation of IL-23 inhibition in PsO by multiple approved therapies, such as Skyrizi (risankizumab) and Tremfya (guselkumab), while leveraging insights from these therapies to improve upon their clinical profile. ORKA-001 is designed to bind a similar epitope to the market-leading anti-IL-23 antibody, Skyrizi, with similar affinity and could achieve much higher exposures in patients due to half-life extension and higher dosing. Skyrizi and Tremfya both have a robust exposure-response relationship, with higher drug exposures leading to higher response rates. Published data indicates that these therapies have not saturated this exposure-response relationship, and ORKA-001 could lead to higher response rates, including higher rates of complete skin clearance, or PASI 100, through increased exposure, even while having more convenient dosing with as few as one or two maintenance doses per year.

- ***Validated IL-23p19 safety profile.*** Existing commercially approved antibodies targeting IL-23 provide a robust precedent for the safety of IL-23 inhibition. Across thousands of patients dosed in dermatology and IBD indications, no correlations have been observed at the patient level between exposure and safety. While we are not pursuing IBD, the approved Skyrizi regimens for Crohn's disease and ulcerative colitis supports the safety of high peak exposures. Peak Skyrizi exposures during the IV induction phase in Crohn's disease and ulcerative colitis are multiple times higher than the anticipated peak ORKA-001

exposures at dose levels we plan to evaluate in PsO. In addition, an exposure-response analysis for Skyrizi in ulcerative colitis showed no relationship between exposures and evaluated safety endpoints in the 12-week induction or 52-week maintenance periods. In this assessment, the top quartile of average exposures was significantly higher than the highest anticipated exposures with ORKA-001 in the same periods.

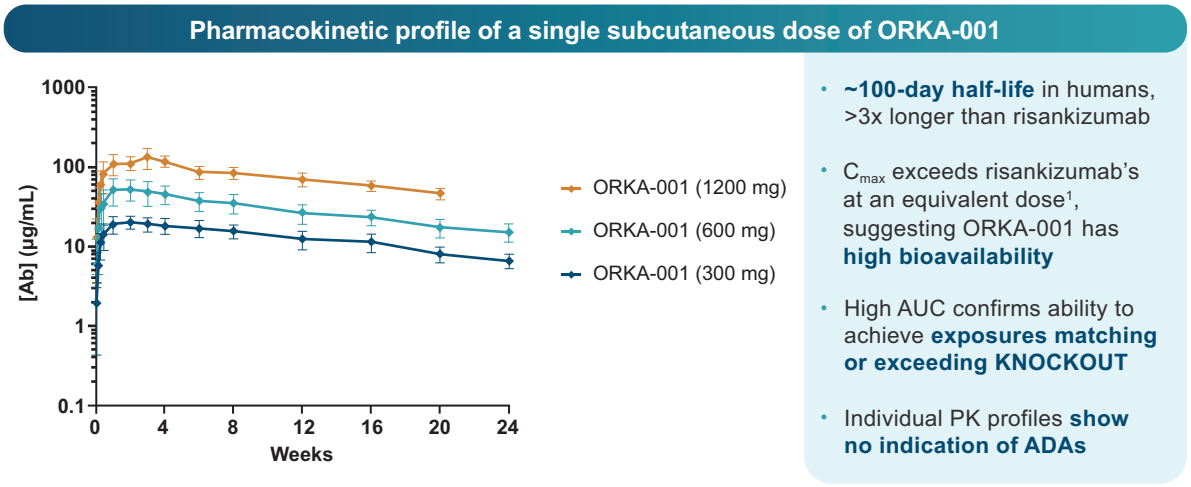
- ***Potential to offer longer term remission to some patients.*** Emerging evidence suggests that IL-23 blockade can modify the disease biology of PsO, possibly leading to durable remissions and preventing the development of PsA. Dr. Andrew Blauvelt, chair of our Scientific Advisory Board, pioneered some of this work by using two- and four-times the approved dose levels of risankizumab to achieve best-in-indication response rates. This study, called KNOCKOUT, showed a robust depletion of TRMs following high dose IL-23 inhibition, which could lead to longer-lasting remissions in some patients. Additional evidence from a study of guselkumab, called GUIDE, showed that intervention early in the disease course can lead to longer treatment-free remissions. In addition, retrospective claims data suggests that treatment with an IL-23 inhibitor could help prevent progression to PsA, though this finding has yet to be confirmed by a prospective clinical trial. Given the high antibody exposures expected with ORKA-001, we believe that ORKA-001 could lead to durable remissions for some patients, especially those with short disease duration. We plan to pursue patient-specific dosing intervals to provide each patient the greatest possible freedom from their disease.

We believe that this target profile for ORKA-001 could offer improved freedom from disease to many patients affected by PsO and represent a step forward in the standard of care.

Clinical Development

We dosed the first participants in a Phase 1 clinical trial of ORKA-001 in healthy volunteers in the fourth quarter of 2024. This trial is a double-blind, placebo-controlled, single ascending dose study evaluating the safety, tolerability, and pharmacokinetics of ORKA-001 in healthy volunteers. The trial enrolled 24 healthy adult participants into three single ascending subcutaneous dose cohorts of 300 mg, 600 mg, and 1200 mg. In September 2025, we announced the interim results at the European Academy of Dermatology and Venereology (EADV) Congress. The data showed that ORKA-001 has a human half-life of approximately 100 days. Single doses of ORKA-001 demonstrated complete and sustained inhibition of STAT3 signaling, a downstream marker of IL-23 activity, in an *ex vivo* assay through 24 weeks. In addition, ORKA-001 was well tolerated at all dose levels, with a favorable safety profile consistent with the anti-IL-23 class. We believe this data supports the key ways in which ORKA-001 could re-define the treatment paradigm in psoriasis: annual dosing, higher efficacy, and off-treatment remission.

ORKA-001 showed a human half-life of approximately 100 days



Notes & Sources: Mean ± SD (N=6 per group). Data cut as of August 6, 2025. (1) Single 300 mg subcutaneous dose of risankizumab in n=6 white healthy volunteers reported in Skyrizi BLA Multi-disciplinary Review and 2019 Khatri (J Clin Pharmacol)

In the third quarter of 2025, we commenced dosing in a Phase 2a proof-of-concept study of ORKA-001 in moderate-to-severe PsO (also known as "EVERLAST-A"). We expect to share Week 16 data for all patients in the second quarter of 2026. In addition, we plan to share longer-term data, including Week 28 for all patients and 52-week follow-up for a portion of the cohort in the second half of 2026. EVERLAST-A enrolled 84 patients randomized 3:1 to receive 600 mg of ORKA-001 at Weeks 0 and 4 or matching placebo. The primary endpoint is PASI 100 at Week 16. At Week 28, patients who have achieved PASI 100 will be randomized 2:1 to an arm where either (1) they do not receive another dose until disease recurrence (to evaluate the possibility of both yearly dosing and extended off-treatment remissions) or (2) they receive 300 mg ORKA-001 every six months. Patients who have not achieved PASI 100 will receive a 300 mg dose every six months. After completing the trial, subjects may have the option to roll over to an open-label extension study.

Additionally, the first patients were dosed in the EVERLAST-B trial in December 2025. EVERLAST-B is designed to enroll approximately 160 patients, is a dose-ranging Phase 2b trial of ORKA-001 in moderate-to-severe PsO patients and will evaluate three dose levels of ORKA-001: 37.5 mg at Week 0, 300 mg at Weeks 0 and 4, and 600 mg at Weeks 0 and 4, versus placebo. The primary endpoint is PASI 100 at Week 16. At Week 28, patients who have achieved PASI 100 will be re-randomized 1:1 to either a 600 mg dose once-yearly or matching placebo. Patients who have not achieved PASI 100 at Week 28 will receive a 300 mg dose every six months. Building on EVERLAST-A, this design will further test the potential for ORKA-001 to achieve yearly dosing, higher efficacy and extended off-treatment remissions. Data from EVERLAST-B is anticipated in 2027.

ORKA-002

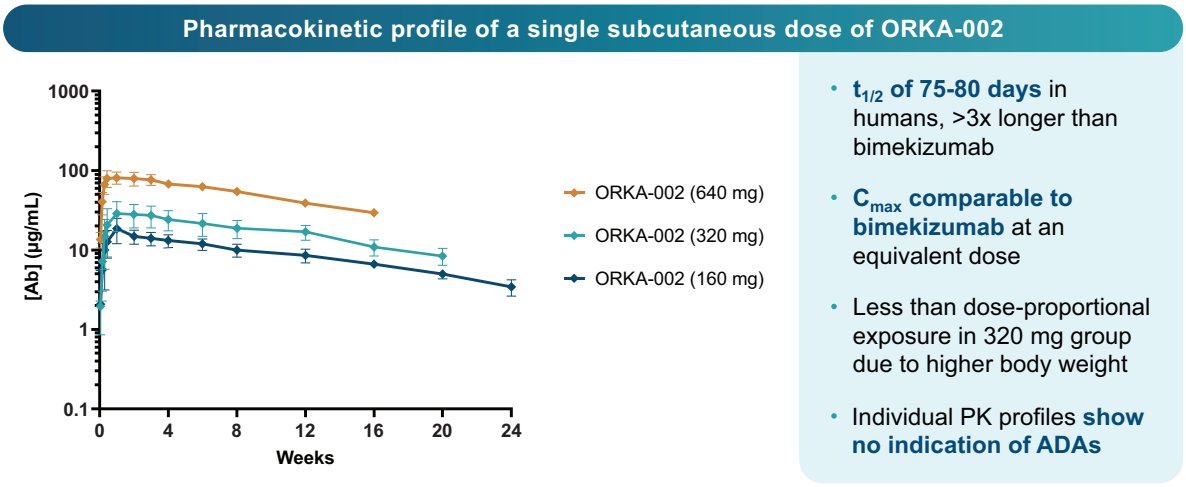
Summary

ORKA-002 is a high affinity, extended half-life mAb designed to target IL-17A/F. Dual inhibition of both IL-17A and IL-17F has shown superior efficacy compared to IL-17A inhibition alone in PsO and other indications, as shown by the performance of Bimzelx (bimekizumab) compared to Cosentyx (secukinumab) and Taltz (ixekizumab) in Phase 3 trials. These therapies all utilize Q4W maintenance dosing in PsO and PsA, except Bimzelx, where Q8W maintenance dosing in PsO patients <120 kg is recommended. By binding IL-17A/F at similar epitopes and affinity ranges as Bimzelx while incorporating half-life extension technology to potentially enable twice-yearly maintenance dosing in PsO and quarterly maintenance dosing in HS, we believe that ORKA-002 could become the leading therapy in the IL-17 class.

Clinical Development

In January 2026, we announced interim findings from the Phase 1 trial of ORKA-002 in healthy volunteers. The study enrolled 24 healthy adult participants into three single-ascending subcutaneous dose cohorts of 160 mg, 320 mg and 640 mg. ORKA-002 showed a half-life of approximately 75-80 days, greater than three times that of bimekizumab, and a comparable Cmax to bimekizumab at equivalent doses based on previously reported bimekizumab data. Pharmacokinetic modeling based on these results supports achieving twice-yearly maintenance dosing in PsO and quarterly maintenance dosing in HS. Additionally, single doses of ORKA-002 demonstrated potent and sustained inhibition of IL-17 signaling in an *ex vivo* assay through 24 weeks. ORKA-002 was well tolerated at all dose levels, with a favorable safety profile consistent with the anti-IL-17 class. The trial remains blinded, and as of January 6, 2026, which was the data cutoff date, all subjects remained on trial.

ORKA-002 showed a half-life of approximately 75-80 days



Notes: Mean ± SD (N=6 per group). Data cut as of January 6, 2026

We initiated ORCA-SURGE, a Phase 2 trial of ORKA-002 in patients with moderate-to-severe PsO, in February 2026. ORCA-SURGE is designed to enroll approximately 160 patients randomized 1:1:1:1 to receive 40 mg, 160 mg or 320 mg of ORKA-002 at Weeks 0 and 4, or matching placebo. The primary endpoint is PASI 100 at Week 16. Maintenance dosing will evaluate the potential for twice-yearly dosing with ORKA-002. Data from ORCA-SURGE is anticipated in 2027.

We see ORKA-002 as highly complementary to ORKA-001, with the potential to provide an improved therapy for the approximately one-quarter to one-third of moderate-to-severe PsO patients who have PsA, as well as for PsO patients with highly resistant skin symptoms that do not respond adequately to an IL-23 inhibitor. Furthermore, ORKA-002 could address indications beyond PsO, including PsA with limited skin involvement, HS, axSpA, and additional I&I diseases. We plan to initiate a Phase 2 trial of ORKA-002 in patients with HS in the second half of 2026.

ORKA-021

The IL-17 and IL-23 inhibitor classes each have distinct advantages. IL-17 inhibitors are generally associated with rapid onset of action and high peak response, while IL-23 inhibitors are typically characterized by less frequent dosing and favorable durability and safety profiles. Sequential use of these two mechanisms has the potential to combine attractive attributes of each class, including the rapid response associated with IL-17 inhibition and the maintenance profile associated with IL-23 inhibition. Accordingly, following ORKA-002 and ORKA-001, we plan to evaluate a sequential combination regimen of ORKA-002 and ORKA-001, which we refer to as “ORKA-021”.

Additional Pipeline Program

We have a third program, ORKA-003, that targets an undisclosed pathway. A core tenet of our strategy is to remain highly focused on I&I diseases, and specifically on inflammatory dermatology conditions. ORKA-003 provides the potential for indication expansion beyond PsO as well as combination opportunities with our more advanced programs. In the future, we may add additional programs to our portfolio beyond ORKA-001, ORKA-002, ORKA-021 and ORKA-003 that fit our strategic focus.

Intellectual Property

We seek to protect the proprietary programs and technologies that we believe are important to our business through a combination of patent protection and other intellectual property strategies. Our intellectual property portfolio is designed to protect our product candidates and related technologies, including patents directed to composition of matter, methods of use and manufacture, and other inventions.

We and Paragon have filed, and may continue to file, patent applications relating to antibodies that target IL-23, including applications covering composition of matter, pharmaceutical formulations, and methods of use, including for ORKA-001. We and Paragon have also filed, and may continue to file, patent applications relating to antibodies that target IL-17, including applications covering composition of matter, pharmaceutical formulations, and methods of use, including for ORKA-002.

We hold exclusive rights to ORKA-001 and ORKA-002, as well as the associated IL-23 and IL-17 patent rights, pursuant to license agreements with Paragon. Certain patent rights covering ORKA-001 are expected to expire in 2045, absent any applicable patent term adjustments or extensions. Patent rights relating to ORKA-002, if issued, are also expected to expire in 2045, absent any applicable patent term adjustments or extensions.

Commercial

If any of our product candidates are approved for commercialization, we intend to commercialize them in the United States and other key markets either independently or through strategic collaborations, with the objective of maximizing the commercial value of our programs. Given our current stage of development, we have not yet established a commercial organization or distribution capabilities. Pursuant to license agreements with Paragon, we hold exclusive worldwide rights to develop and commercialize ORKA-001 and ORKA-002.

Manufacturing

We do not currently own or operate facilities for product manufacturing, testing, storage, and distribution. We have contracted and expect to continue to contract with third parties for the manufacture and distribution of our product candidates. Because we rely on contract manufacturers, we employ personnel with extensive technical, manufacturing, analytical, and quality experience. Our team has deep knowledge and understanding of the regulations that govern manufacturing, documentation, quality assurance, and quality control of drug supply that are required to support our regulatory filings.

Competition

The biotechnology and biopharmaceutical industries are characterized by continuing technological advancement and significant competition. While we believe that our programs, technology, development experience and scientific knowledge provide us with competitive advantages, we face competition from major pharmaceutical and biotechnology companies, academic institutions, governmental agencies, and public and private research institutions, among others. Any product candidates that we successfully develop and commercialize will compete with existing therapies and therapies that may become available in the future. 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, conducting clinical trials, obtaining regulatory approvals, and marketing approved products 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, patient enrollment for clinical trials as well as in acquiring technologies complementary to, or necessary for, our programs.

Key competitive factors affecting the success of all our product candidates that we develop, if approved, are likely to be efficacy, safety, convenience, presentation, price, the level of generic competition, and the availability of reimbursement from government and other third-party payors. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for our products, which could result in our competitors establishing a strong market position before we are able to enter the market.

Specifically, there are several companies developing or marketing treatments that may be approved for the same indications and/or diseases as our two most advanced programs, ORKA-001 and ORKA-002, including major pharmaceutical companies. We have generated early-stage clinical data for certain programs, and there can be no assurance that early clinical results will be predictive of later-stage outcomes.

There are several approved biologic therapies for the treatment of moderate-to-severe PsO. These include mAbs targeting IL-23, such as Skyrizi (risankizumab) from AbbVie, Tremfya (guselkumab) from Janssen, Ilumya (tildrakizumab) from Sun Pharma, also marketed as Ilumetri by Almirall in Europe, and Pecondle (picankibart) from Innovent Biologics, which has been approved in China, which all target the p19 subunit, and Stelara (ustekinumab) from Janssen, which targets the p40 subunit; mAbs targeting IL-17, such as Bimzelx (bimekizumab) from UCB, which targets IL-17A/F, Cosentyx (secukinumab) from Novartis and Taltz (ixekizumab) from Eli Lilly, which both target IL-17A, and Siliq (brodalumab) from Ortho Dermatologics, also marketed as Kyntheum by LEO Pharma in Europe, which targets IL-17 receptor A; and biologics targeting TNF-α, such as Humira (adalimumab) from AbbVie, Enbrel (etanercept) from Amgen, and Remicade (infliximab) from Janssen, and various biosimilar versions of each. In addition, there are several approved oral medicines in these indications, including the phosphodiesterase-4 (PDE4) inhibitor Otezla (apremilast) from Amgen and the tyrosine kinase 2 (TYK2) inhibitor Sotyktu (deucravacitinib) from Bristol-Myers Squibb. Many of these therapies are also approved or in development for PsA, HS, axSpA, and other I&I indications.

In addition, we are aware of several product candidates in clinical development for moderate-to-severe PsO, along with PsA, HS, axSpA, and other indications. These include the biologic sonelokimab from MoonLake Immunotherapeutics targeting IL-17A/F, and several oral agents in development, including JNJ-2113 (icotrokinra) from Janssen targeting the IL-23 receptor, DC-853 (simepdekinra) from Eli Lilly targeting IL-17A, PN-881 from Protagonist targeting IL-17A/F, and TAK-279 (zasocitinib) from Takeda and ESK-001 (envudeucitinib) from Alumis, both targeting TYK2. AbbVie has also announced plans to initiate a Phase 1 clinical study of a long-acting IL-23p19 inhibitor in 2026.

Significant Agreements

Paragon Therapeutics — Option Agreements and License Agreements

In March 2024, we entered into two Antibody Discovery and Option Agreements with Paragon and Paruka Holding, LLC ("Paruka") (each, an "Option Agreement"), pursuant to which we initiated certain research programs with Paragon focusing on discovering, generating, identifying and/or characterizing antibodies directed to a particular target, including for IL-23 and IL-17A/F for ORKA-001 and ORKA-002, respectively. In September 2024, we exercised our exclusive option to acquire certain rights to ORKA-001, and in December 2024, we entered into a corresponding license agreement with Paragon pursuant to which Paragon granted us a royalty-bearing, world-wide, exclusive license to develop, manufacture, commercialize or otherwise exploit certain antibodies and products targeting IL-23 in all fields other than the field of inflammatory bowel disease. In December 2024, we exercised our exclusive option to acquire certain rights to ORKA-002, and in February 2025, we entered into the corresponding license agreement with Paragon pursuant to which Paragon granted us a royalty-bearing, world-wide, exclusive license to develop, manufacture, commercialize or otherwise exploit certain antibodies and products targeting IL-17A/F in all fields (collectively, the "License Agreements").

Pursuant to each of the License Agreements, Paragon has agreed not to conduct any new campaigns that generate anti-IL-23 monospecific antibodies or anti-IL-17A/F monospecific antibodies in the respective agreed-upon fields. Each of the ORKA-001 and ORKA-002 License Agreements may be terminated on 60 days' notice to Paragon, on material breach without cure, and on a party's insolvency or bankruptcy to the extent permitted by law.

Pursuant to the terms of each of the License Agreements, we are obligated to pay Paragon non-refundable milestone payments of up to $12.0 million under each respective agreement upon the achievement of certain clinical development milestones and up to $10.0 million under each respective agreement upon the achievement of certain regulatory milestones. As of December 31, 2025, we have incurred and expensed milestone payments of $7.0 million and $4.0 million in connection with the ORKA-001 License Agreement and the ORKA-002 License Agreement, respectively. In addition, we are obligated to pay Paragon a low single-digit percentage royalty for antibody products for each of ORKA-001 and ORKA-002. For each of the License Agreements, the royalty term ends on the later of (i) the last-to-expire licensed patent or our patent directed to the manufacture, use or sale of a licensed antibody in the country at issue or (ii) 12 years from the date of first sale of our product. There is also a royalty step-down if there is no Paragon patent in effect during the royalty term for each program.

Additionally, as part of the Option Agreements and the additional option agreement described in the following paragraph, on December 31, 2024, we settled our 2024 obligations under the Paruka Warrant Obligation by issuing Paruka a warrant to purchase 596,930 shares of company common stock at an exercise price of $19.39 per share, and on December 12, 2025, we settled our 2025 obligations under the Paruka Warrant Obligation by issuing Paruka a warrant to purchase 375,000 shares of company common stock at an exercise price of $30.18 per share.

In December 2025, we entered into an additional option agreement for an antibody with Paragon and Paruka to enter into a license agreement, which we exercised in December 2025. For the year ended December 31, 2025 we incurred $1.5 million related to this additional option agreement, which was recognized as research and development expense. Per the terms of this option agreement, once we enter into the corresponding license agreement, we will be required to make non-refundable milestone payments to Paragon of up to $12.0 million under the agreement upon the achievement of certain clinical development milestones, up to $10.0 million under the agreement upon the achievement of certain regulatory milestones, as well as a low single-digit percentage royalty for antibody products beginning on the first commercial sale. As of December 31, 2025, we have not entered into a license agreement with Paragon and Paruka related to this additional option agreement.

Cell Line License Agreement

In March 2024, we entered into the Cell Line License Agreement (the "Cell Line License Agreement") with WuXi Biologics Ireland Limited ("WuXi Biologics"). Under the Cell Line License Agreement, we received a non-exclusive, worldwide, sublicensable license to certain of WuXi Biologics' know-how, cell line, biological materials (the "WuXi Biologics Licensed Technology") and media and feeds to make, have made, use, sell and import certain therapeutic products produced through the use of the cell line licensed by WuXi Biologics under the Cell Line License Agreement (the "WuXi Biologics Licensed Products"). Specifically, the WuXi Biologics Licensed Technology is used in certain manufacturing activities in support of the ORKA-001 and ORKA-002 programs.

In consideration for the license, we agreed to pay WuXi Biologics a non-refundable license fee of $150,000. Additionally, to the extent that we manufacture our commercial supplies of bulk drug product for ORKA-001 and/or ORKA-002 under such license with a manufacturer other than WuXi Biologics or its affiliates, we are required to make royalty payments to WuXi Biologics at a rate of less than one percent of net sales of WuXi Biologics Licensed Products manufactured by the third-party manufacturer. Pursuant to an amendment to the Cell Line License Agreement effective in November 2024, a provision was added that permits the royalties owed under the agreement to be bought out on a product-by-product basis for a lump-sum payment.

The Cell Line License Agreement will continue indefinitely unless terminated (i) by us upon six months' prior written notice and our payment of all undisputed amounts due to WuXi Biologics through the effective date of termination, (ii) by WuXi Biologics for a material breach by us that remains uncured for 60 days after written notice, (iii) by WuXi Biologics if we fail to make a payment and such failure continues for 30 days after receiving notice of such failure, or (iv) by either party upon the other party's bankruptcy.

Government Regulation

The FDA and other regulatory authorities at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring, and post-approval reporting of biologics such as those we are developing. We, along with our third-party contractors, will be required to navigate the various preclinical, clinical, and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates. Generally, before a new therapeutic product can be marketed, considerable data demonstrating a biological product candidate's quality, safety, purity, and potency, or a small molecule drug candidate's quality, safety, and efficacy, must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority. For biological product candidates, potency is similar to efficacy and is interpreted to mean the specific ability or capacity of the product, as indicated by appropriate laboratory tests or by adequately controlled clinical data obtained through the administration of the product in the manner intended, to effect a given result.

Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process, or post-marketing may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications from the sponsor, withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement, and civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on our company and our products or product candidates.

United States Biologics Regulation

In the United States, biological products are subject to regulation under the Federal Food, Drug, and Cosmetic Act ("FDCA"), the Public Health Service Act ("PHSA"), and other federal, state, local, and foreign statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, and local statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process, or following approval may subject an applicant to administrative action and judicial sanctions. The process required by the FDA before biologic product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's current Good Laboratory Practices ("GLP") regulation;
- submission to the FDA of an IND, which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an independent institutional review board ("IRB") or ethics committee at each clinical site before the trial is commenced;
- manufacture of the proposed biologic candidate in accordance with current Good Manufacturing Practices ("cGMPs");
- performance of adequate and well-controlled human clinical trials in accordance with current Good Clinical Practice ("GCP") requirements to establish the safety, purity, and potency of the proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a BLA, after completion of all pivotal clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMPs, and to assure that the facilities, methods, and controls are adequate to preserve the biological product's continued safety, purity, and potency, and of selected clinical investigation sites to assess compliance with GCP; and
- FDA review and approval of a BLA to permit commercial marketing of the product for particular indications for use in the United States.

Preclinical and Clinical Development

Once a therapeutic product candidate is identified for development, it must undergo preclinical studies before commencing any testing in humans. Preclinical studies include laboratory evaluations of product chemistry, formulation, and stability, as well as studies to evaluate the candidate's potential for efficacy and toxicity in animals. The conduct of preclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements, including current GLPs.

Prior to beginning any clinical trial with a product candidate in the United States, we must submit an IND application to the FDA. An IND application is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND application is on the general investigational plan, supportive nonclinical evaluations, and the protocol or protocols for clinical trials. The IND includes results of animal and

in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product, chemistry, manufacturing and controls information, and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with current GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the trial until completed.

Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some trials also include oversight by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or data monitoring committee, which provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries.

Human clinical trials are typically conducted in three sequential phases that may overlap.

- Phase 1. The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism, and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.

- Phase 2. The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule, and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

- Phase 3. The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may be made a condition to approval of the BLA. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, methods must be developed for testing the safety, purity, and potency of the biologic. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its claimed shelf life.

A sponsor may choose, but is not required, to conduct a foreign clinical trial under an IND. When a foreign clinical trial is conducted under an IND, all IND requirements must be met unless waived. When the foreign clinical trial is not conducted under an IND, the sponsor must ensure that the trial complies with certain FDA regulatory requirements in order to use the trial as support of a BLA, including that the trial was conducted in accordance with

GCP, review and approval by an independent ethics committee, use of proper procedures for obtaining informed consent from subjects, and the FDA is able to validate the data from the trial through an onsite inspection if the FDA deems such inspection necessary. The GCP requirements encompass both ethical and data integrity standards for clinical studies.

BLA Submission and Review

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies, and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of the product, or from a number of alternative sources, including trials initiated and sponsored by investigators. The submission of a BLA requires payment of a substantial application user fee to the FDA, unless a waiver or exemption applies.

In addition, under the Pediatric Research Equity Act ("PREA"), a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the biological product candidate for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective, unless a different timeline has been previously agreed upon by the FDA, through approval of a pediatric study plan, as described below. The Food and Drug Administration Safety and Innovation Act requires that a sponsor who is planning to submit a marketing application for a biological product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial pediatric study plan ("PSP") within sixty days after an end-of-Phase 2 meeting or as may be agreed between the sponsor and FDA. Unless otherwise required by regulation, PREA does not apply to any biological product for an indication for which orphan designation has been granted.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. Once a BLA has been accepted for filing, the FDA's goal is to review standard applications within ten months after the FDA accepts the application for filing, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process may also be extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure, and potent and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity, and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCPs and data integrity of the submitted clinical trial data. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response letter will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response letter without first conducting required inspections, testing submitted product

lots, and/or reviewing proposed labeling. In issuing the Complete Response letter, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information, and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy ("REMS") to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include requirements for medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-marketing studies, and/or surveillance in addition to that required of every approved product to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

Combination Therapy

Combination therapy is a treatment modality that involves the use of two or more drugs to be used in combination to treat a disease or condition. If those drugs are combined in one dosage form, such as a single injection, that is known as a fixed dose combination product and it is reviewed pursuant to the FDA's Combination Rule at 21 CFR 300.50. The rule provides that two or more drugs may be combined in a single dosage form when each component contributes to the claimed effects and the dosage of each component (amount, frequency, duration) is such that the combination is safe and effective for a significant patient population requiring such concurrent therapy as defined in the labeling for the drug. However, not all combination therapy falls under the category of a fixed dose combination. For example, the FDA recognizes that two drugs in separate dosage forms and in separate packaging, that otherwise might be administered as monotherapy for an indication, also may be used in combination for the same indication. In 2013, the FDA issued guidance to assist sponsors that were developing the range of combination therapies that fall outside the category of fixed dose combinations. That guidance provides recommendations and advice on such topics as: (1) assessment at the outset whether two or more therapies are appropriate for use in combination; (2) guiding principles for nonclinical and clinical development of the combination; (3) options for regulatory pathways to seek marketing approval of the combination; and (4) post-marketing safety monitoring and reporting obligations. Given the wide range of potential combination therapy variations, the FDA indicated it intends to assess each potential combination on a case-by case basis and encouraged sponsors to engage in early and regular consultation with the relevant review division at the agency throughout the development process for its proposed combination.

Regulation of Combination Products

Certain therapeutic products are comprised of multiple components, such as drug components, biologic components, and device components, that would normally be subject to different regulatory frameworks by the FDA and frequently regulated by different centers at the FDA. These products are known as combination products. Under the FDCA, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. The determination of which center will be the lead center is based on the "primary mode of action" of the combination product. Thus, if the primary mode of action of a drug/biologic-device combination product is attributable to the drug or biological product, the FDA center responsible for premarket review of the drug or biological product would have primary jurisdiction for the combination product. The FDA has also established the Office of Combination Products to address issues surrounding combination products and provide more certainty to the regulatory review process. That office serves as a focal point for combination product issues for agency reviewers and industry. It is also responsible for developing guidance and regulations to clarify the regulation of combination products, and for assignment of the FDA center that has primary jurisdiction for review of combination products where the jurisdiction is unclear or in dispute. A combination product with a primary mode of action attributable to the drug or biologic component generally would be reviewed and approved pursuant to the drug or biologic approval processes set forth in the FDCA. In reviewing the new drug application ("NDA") or BLA for such a product,

however, FDA reviewers would consult with their counterparts in the FDA's Center for Devices and Radiological Health to ensure that the device component of the combination product met applicable requirements regarding safety, effectiveness, durability, and performance. In addition, under FDA regulations, combination products are subject to cGMP requirements applicable to both drugs and devices, including the Quality System Regulation applicable to medical devices.

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. After a BLA is approved for a biological product, the product also may be subject to official lot release. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA also may perform certain confirmatory tests on lots of some products before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, and potency or effectiveness of biologics. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which the FDA assesses an annual program fee for each product identified in an approved BLA. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA review and approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMPs and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain compliance with cGMPs and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-marketing studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market, or product recalls;
- fines, warning letters, or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases, and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and consistent with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label uses of their products. Additionally, promotional material for approved biologic products must be submitted to the FDA in conjunction with their first use.

Biosimilars and Reference Product Exclusivity

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, 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 highly similar, or "biosimilar," to or interchangeable with an FDA-approved reference biological product. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, is generally shown through analytical studies, animal studies, and a clinical trial or trials. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. A product shown to be biosimilar or interchangeable with an FDA-approved reference biological product may rely in part on the FDA's previous determination of safety and effectiveness for the reference product for approval, which can potentially reduce the cost and time required to obtain approval to market the product. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation and the FDA has issued guidance documents intended to inform prospective applicants and facilitate the development of proposed biosimilars and interchangeable biosimilars, as well as to describe the FDA's interpretation of certain statutory requirements added by the BPCIA.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. Additionally, many states have passed laws concerning the ability of pharmacies to substitute biosimilar and interchangeable products for the reference product.

A reference biologic is granted twelve years of exclusivity from the time of first licensure (BLA approval) of the reference product. The first biologic product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against other biologics submitted under the abbreviated approval pathway for the lesser of (i) one year after the first commercial marketing, (ii) 18 months after approval if there is no legal challenge, (iii) 18 months after the resolution in the applicant's favor of a lawsuit challenging the biologics' patents if an application has been submitted, or (iv) 42 months after the application has been approved if a lawsuit is ongoing within the 42-month period.

A biological product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

As discussed below, the Inflation Reduction Act of 2022 ("IRA") is a significant new law that intends to foster generic and biosimilar competition and to lower drug and biologic costs.

Patent Term Extension

In the United States, after a BLA is approved, owners of relevant drug patents may apply for up to a five-year patent extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory process. The allowable patent term extension is typically calculated as one-half the time between, the latter of the effective date of an IND and issue date of the patent for which extension is sought, and the submission date of a BLA, plus the time between BLA submission date and the BLA approval date up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue licensure with due diligence. The total patent term after the extension may not exceed 14 years from the date of product licensure. Only one patent applicable to a licensed biological product is eligible for extension and only those claims covering the product, a method for using it, or a method for manufacturing it may be extended and the application for the extension must be submitted prior to the expiration of the patent in question. However, a company may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Some, but not all, foreign jurisdictions possess patent term extension or other additional patent exclusivity mechanisms that may be more or less stringent and comprehensive than those of the United States.

Other Healthcare Laws and Compliance Requirements

Biopharmaceutical manufacturers, particularly manufacturers of marketed products, are subject to healthcare regulation and enforcement by federal, state, and local government authorities in the U.S., as well as by foreign jurisdictions. Biopharmaceutical manufacturers must comply with various federal, state, and local laws targeting fraud and abuse in the healthcare industry, including anti-kickback and false claims laws.

The federal Anti-Kickback Statute ("AKS") generally prohibits, among other things, a pharmaceutical manufacturer from directly or indirectly soliciting, offering, receiving, or paying any remuneration, in cash or in kind, where one purpose is either to induce the referral of an individual for, or the purchase or prescription of, a particular drug that is payable by a federal health care program, including Medicare or Medicaid. A person or entity does not need to have actual knowledge of the statute or a specific intent to violate the statute.

There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but protection is available only if all requirements are met. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. A claim arising from a violation of the federal Anti-Kickback Statute also constitutes a fraudulent claim for purposes of the False Claims Act ("FCA"). Other federal and state anti-kickback statutes exist. For example, another healthcare anti-kickback statute prohibits certain payments related to referrals of patients to certain providers (such as clinical laboratories) and applies to services reimbursed by private health plans as well as government health care programs.

Federal and state false claims laws, such as the FCA, generally prohibit anyone from knowingly and willfully, among other activities, presenting or causing to be presented, payment to third party payors (including Medicare and Medicaid) claims for drugs or services that are false or fraudulent. Pharmaceutical and other healthcare companies have been prosecuted under these laws for engaging in a variety of different types of conduct that "caused" the submission of false claims to federal healthcare programs. Such laws are not always limited to activities involving government programs or payors. For example, a federal healthcare fraud statute prohibits the knowing and willful execution, or attempt to execute, a scheme to defraud a health care benefit program, including private health plans, or obtain, through false or fraudulent pretenses, money or property owned by, or under the custody or control of, such a health care benefit program. Laws and regulations have also been enacted by the federal government and various states to regulate the sales and marketing practices of pharmaceutical manufacturers. The laws and regulations generally limit financial interactions between manufacturers and health care providers; require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government; and/or require disclosure to the government and/or public of financial

interactions (so-called "sunshine laws" and "sunshine reporting"). State and local laws may also require disclosure of pharmaceutical pricing information and marketing expenditures or licensure of sales representatives. Manufacturers must also submit information to the FDA on the identity and quantity of drug samples requested and distributed by a manufacturer during each year.

Biopharmaceutical manufacturers are also subject to federal pricing and price reporting laws. Such laws require manufacturers to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on approved products. The laws may also require biopharmaceutical manufacturers to offer products at discounted prices to specific government programs or specific purchasers as a condition for participation in certain government health benefit programs. Federal consumer protection and unfair competition laws broadly regulate marketplace activities and activities that potentially harm consumers.

The distribution of biological products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage, and security requirements intended to prevent the unauthorized sale of such products. Sanctions for the violation of healthcare laws vary by law but may be significant and compliance is challenging. For example, violations of fraud and abuse laws may be punishable by criminal or civil sanctions, including fines and civil monetary penalties, and/or exclusion from federal health care programs (including Medicare and Medicaid). The scope of the federal and the various analogous state anti-kickback, false claims, and similar fraud and abuse laws vary, but is generally broad. Many of the fraud and abuse laws and regulations contain ambiguous requirements or require administrative guidance for implementation. Federal and state authorities are paying increased attention to enforcement of these laws within the pharmaceutical industry, and private individuals have been active in alleging violations of the laws and bringing suits on behalf of the government under the FCA as evidenced by numerous significant settlements. Violations of international fraud and abuse laws could result in similar penalties, including exclusion from participation in health programs outside the U.S.

Data Privacy and Security

Biopharmaceutical companies are subject to numerous and evolving U.S. federal and state laws and regulations governing the collection, use, disclosure, transfer, and security of personal information, including health-related information, any of which may impose operational constraints, create compliance complexity, and increase enforcement and litigation exposure. U.S. federal and state frameworks include HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and its implementing regulations (including the Privacy, Security, Breach Notification, and Enforcement Rules), state health information privacy laws, state data breach notification laws, a growing number of state comprehensive consumer privacy laws, as well as other consumer protection laws and regulations that could apply to our operations or the operations of our partners. Certain sector and data specific laws, including those governing marketing communications, data security, and the sale or transfer of certain categories of sensitive data, as well as evolving state tort and other common law restrictions that may govern privacy and data security practices may be tested by the court system and enforced by enforcement authorities, may apply to parts of our operations as well as to the operations of our partners.

HIPAA imposes standards for the privacy of protected health information ("PHI"), the security of electronic PHI, breach notification to individuals and regulators, and enforcement. HIPAA applies directly to "covered entities" (health care providers, health plans, and health care clearinghouses), as well as their "business associates" and their covered subcontractors that perform certain services that involve using, disclosing, creating, receiving, maintaining, or transmitting individually identifiable PHI for or on behalf of such covered entities. Requirements imposed by HIPAA on covered entities and business associates include: (i) entering into agreements that require business associates and their covered subcontracts to protect PHI provided by the covered entity against improper use or disclosure; (ii) complying with HIPAA privacy standards that limit the use and disclosure of information about a patient's past, present, or future physical or mental health condition, or the patient's receipt of health care, where the information identifies, or could reasonably be used to identify, the individual; (iii) implementing administrative, physical, and technical safeguards to ensure the confidentiality, integrity, and availability of electronic PHI and to protect against reasonably anticipated threats, hazards, or impermissible uses or disclosure; and (iv) reporting of breaches of unsecured PHI to affected individuals and, where applicable, regulators. Entities that violate HIPAA may face substantial civil, criminal, and administrative penalties, additional reporting and oversight obligations, and may be required to enter into resolution agreements and corrective action plans with the U.S. Department of Health and Human Services. Covered entities and

business associates can also be held liable for violations committed by their agents, including downstream business associates, and HITECH has increased applicable penalties and authorized state attorneys general to bring civil action in federal court to enforce HIPAA and seek damages, injunctive relief and attorneys' fees.

In addition, several states have enacted or are implementing health data specific statutes outside HIPAA that broadly regulate the collection, use, and disclosure of "consumer health data" including certain research analytics, website, and marketing activities. These laws may impose consent, notice, contract, and data security obligations, create limitations on sharing with third parties and processors, and provide private rights of action or enhanced enforcement, which could affect aspects of our operations. Even when HIPAA and state health information privacy laws do not apply, according to the FTC and state Attorneys General, violating consumers' privacy rights or failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act and state consumer protection laws.

In addition, certain state laws, such as the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 ("CCPA") and other comprehensive state privacy laws, together with their implementing regulations, establish individual rights regarding personal information, impose notice, purpose-limitation, data minimization, and security obligations, and require specific contracts with service providers and other third parties. Some of these laws also require honoring opt-out signals for targeted advertising or certain profiling, restrict processing of "sensitive" personal information, and mandate assessments for higher-risk processing activities. Scope and exemptions vary by state: for example, the CCPA applies to personal information of consumers, business representatives, and employees, includes additional protections for "sensitive personal information", and generally excludes PHI subject to HIPAA; other states may exempt entities regulated by HIPAA or data processed in the context of clinical trials, or neither, which complicates compliance and increases legal risks and costs. Other state data breach notification statutes, like the New York SHIELD Act, require notification to affected individuals and, in some cases, regulators and consumer reporting agencies following certain security incidents.

Use of artificial intelligence ("AI") and machine learning technologies in research, analytics, and business operations is subject to a rapidly evolving legal and regulatory landscape. Federal and state authorities are increasingly focused on the responsible use of AI, including requirements for transparency, accountability, and the mitigation of algorithmic bias and discrimination. Several states have enacted or are considering laws that regulate the use of AI in processing personal information, mandate impact assessments for high-risk AI applications, and require disclosures regarding automated decision-making. We may be required to implement measures to assess and address potential biases in AI models, ensure explainability and fairness, and provide individuals with rights regarding automated processing of their data. In addition, federal agencies such as the FDA have issued guidance on the use of AI in medical device development and clinical research, which may impact our business. As regulatory expectations continue to develop, we may need to update our policies, procedures, and technical controls to ensure compliance with AI-related requirements. The requirements of these laws and regulations continue to develop, and new laws, amendments, or interpretive guidance may require us to modify our practices.

Coverage and Reimbursement

In the U.S. and other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from government healthcare programs, such as Medicare and Medicaid, and private payors are critical to new product acceptance. Our ability to successfully commercialize our product candidates, if and when approved, will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government healthcare programs, private health insurers, and other organizations.

Within the U.S., no uniform policy for coverage and reimbursement exists and coverage and reimbursement for drugs products can differ significantly from payor to payor, and a third party payor's decision to cover a particular drug product does not ensure that other payors will also provide coverage for that drug product. Factors payors may consider in determining coverage include whether the product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;

- cost-effective; and
- neither experimental nor investigational.

Third-party payors are increasingly challenging the prices charged for pharmaceutical or biological products and related services, examining the medical necessity and reviewing the cost effectiveness of such products and services. For products administered under the supervision of a physician, inadequate reimbursement for the product itself or the treatment or procedure in which the product is used may adversely impact physician utilization. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product that receives approval. Decreases in third-party reimbursement for any product or a decision by a third-party not to cover a product could reduce physician usage and patient demand for the product.

Finally, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, drug pricing in the European Union ("EU") is primarily at the national level, with each member state setting its own prices and reimbursement rules. To obtain reimbursement or pricing approval, countries may require the completion of clinical trials to establish relative clinical effectiveness to guide cost effectiveness assessment of anew treatment method to currently available therapies. A member state may approve a specific price for the medicinal product or implement a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will grant favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the EU do not follow price structures of the United States and generally prices tend to be significantly lower.

Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of reform proposals to change the healthcare system. There is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access.

The ACA, which was enacted in March 2010, substantially changed the way healthcare is financed by both governmental and private insurers in the United States, and significantly affected the pharmaceutical industry. The ACA contains a number of provisions of particular import to the pharmaceutical and biotechnology industries, including, but not limited to, those governing enrollment in federal healthcare programs, a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future.

In the U.S., in recent years, the pharmaceutical industry has been a particular focus of healthcare reform efforts and has been significantly affected by major legislative, administrative and executive initiatives. For example, the Inflation Reduction Act of 2022 (IRA) included a number of changes intended to address rising prescription drug prices in Medicare Parts B and D. These changes included caps on Medicare Part D out-of-pocket costs, Medicare Part B and Part D drug price inflation rebates, a new Medicare Part D manufacturer discount drug program (replacing the previous coverage gap discount program) and a drug price negotiation program for certain high-spend Medicare Part B and D drugs. The IRA has had and will likely continue to have a significant impact on the pharmaceutical industry. Beyond the IRA, changes to Medicaid effective in 2024 eliminated the Medicaid rebate cap. Additionally, changes to certain Medicare price reporting requirements for drugs beginning in 2026 will likely increase the administrative and compliance burden for manufacturers.

Recently, drug pricing and payment has been subject to a number of reform initiatives. For example, President Trump issued an Executive Order in April 2025 with multiple directives aimed at lowering drug prices, including refining the Medicare drug price negotiation program established by the IRA; accelerating competition for high-cost prescription drugs by accelerating approval of generics and biosimilars and facilitating the process for re-classifying prescription drugs as over-the-counter drugs; and increasing drug importation. In May 2025, President Trump issued another Executive Order that directed government agencies and officials to identify most-favored nation pricing targets for prescription drugs (and looked to pharmaceutical manufacturers to make significant progress towards

delivering target prices to patients); prevent foreign countries from disproportionately shifting the cost of global pharmaceutical research and development to the United States; and facilitate direct-to-consumer purchasing programs for pharmaceutical manufacturers to sell their products to patients at the most-favored-nation price. In the wake of the Executive Orders and related executive initiatives, a number of pharmaceutical manufacturers have announced direct-to-consumer offerings with discounted prices and/or reached agreement with the federal government regarding pricing for drugs, including prices for Medicaid drugs and newly launched products. A website sponsored by the federal government that is anticipated to offer pharmaceutical direct-to-consumer channels has also been announced. Federal agencies are developing new drug pricing pilot programs, such as a voluntary Medicaid initiative which would authorize the federal government to negotiate Medicaid supplemental rebates with participating manufacturers on behalf of state Medicaid programs, in exchange for standardized coverage criteria for participating manufacturer drugs, and the proposed Medicare Part B and Part D pilot models that, if finalized as proposed, would replace existing inflation-based Medicare rebates with rebates determined on the basis of international prices, for drugs and patients subject to the model. Many of these reform initiatives would require additional legal and/or administrative action to implement and may be subject to legal challenge.

At the state level, individual states are increasingly implementing initiatives designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and measures to encourage importation from other countries and bulk purchasing. For example, certain states have formed Prescription Drug Affordability Boards that assert authority to set reimbursement rates and/or drug pricing in the state. States are also increasingly expanding or changing Medicaid supplemental rebate programs to secure additional rebates from manufacturers in exchange for drug coverage and to limit coverage of certain drugs for certain Medicaid patients or to all Medicaid patients. These and other future state-level reform activities could negatively affect Medicaid coverage and reimbursement for our products.

Other recent government actions also may affect prices or payments for prescription drugs. For example, the Trump Administration's recently announced tariff on branded or patented drugs may adversely impact our ability to realize an adequate return on the sale of drug products (if approved) that are imported from abroad or manufactured using products or materials imported from abroad. The timeline for implementation of this tariff has not yet been finalized. As another example, the Budget Control Act of 2011, as amended, resulted in the imposition of reductions in Medicare (but not Medicaid) payments to providers in 2013 and will remain in effect into 2032 unless additional Congressional action is taken. Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented and/or any significant taxes or fees that may be imposed on us could have an adverse impact on our results of operations.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state measures designed to, among other things, reduce the cost of prescription drugs, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, in May 2019, CMS adopted a final rule allowing Medicare Advantage Plans the option to use step therapy for Part B drugs, permitting Medicare Part D plans to apply certain utilization controls to new starts of five of the six protected class drugs, and requiring the Explanation of Benefits for Part D beneficiaries to disclose drug price increases and lower cost therapeutic alternatives, which went into effect on January 1, 2021.

Other Government Regulation Outside of the United States

In addition to regulations in the United States, we are subject to a variety of regulations in other jurisdictions governing, among other things, research and development, clinical trials, testing, manufacturing, safety, efficacy, quality control, labeling, packaging, storage, record keeping, distribution, reporting, export and import, advertising, marketing and other promotional practices involving biological products as well as authorization, approval as well as post-approval monitoring and reporting of our products. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials.

The requirements and process governing the conduct of clinical trials, including requirements to conduct additional clinical trials, product licensing, safety reporting, post-authorization requirements, marketing and promotion, interactions with healthcare professionals, pricing and reimbursement may vary widely from country to country. No action can be taken to market any product in a country until an appropriate marketing approval has been granted by the regulatory authorities in that country. The current approval process varies from country to country, and the time spent in gaining approval may vary from that required for FDA approval. In certain countries, the sales price of a product must also be agreed or approved by payors or the respective national health system before commercial launch. The pricing review period often begins after marketing approval. Although a product may receive marketing approval from a regulatory authority, the price agreed upon during the review process may not be commercially sustainable to justify a commercial launch in those countries.

Regulation in the European Union

European Data and Security Laws

The collection and use of personal health data and other personal data in the EU is governed by the provisions of the European General Data Protection Regulation (EU) 2016/679 ("GDPR"), which came into force in May 2018, and related data protection laws in individual EU Member States. The GDPR imposes a number of strict obligations and restrictions on the ability to process, including collecting, analyzing and transferring, personal data of individuals, in particular with respect to health data from clinical trials and adverse event reporting. The GDPR includes requirements relating to the legal basis of the processing (such as consent of the individuals to whom the personal data relates), the information provided to the individuals prior to processing their personal data, the personal data breaches which may have to be notified to the national data protection authorities and data subjects, the measures to be taken when engaging processors, and the security and confidentiality of the personal data. EU Member States may also impose additional requirements in relation to health, genetic and biometric data through their national legislation.

In addition, the GDPR imposes specific restrictions on the transfer of personal data to countries outside of the European Economic Area ("EEA") that are not considered by the European Commission ("EC") to provide an adequate level of data protection. Appropriate safeguards are required to enable such transfers. Among the appropriate safeguards that can be used, the data exporter may use the standard contractual clauses ("SCCs"). When relying on SCCs, data exporters are also required to conduct a transfer risk assessment to verify if anything in the law and/or practices of the third country may impinge on the effectiveness of the SCCs in the context of the transfer at stake and, if so, to identify and adopt supplementary measures that are necessary to bring the level of protection of the data transferred to the EU standard of essential equivalence. Where no supplementary measure is suitable, the data exporter should avoid, suspend or terminate the transfer. With regard to the transfer of data from the EEA to the United States, on July 10, 2023, the EC adopted its adequacy decision for the EU-US Data Privacy Framework. On the basis of the new adequacy decision, personal data can flow from the EEA to U.S. companies participating in the framework. With regard to the transfer of data from the EU to the United Kingdom ("UK"), personal data may freely flow from the EEA to the UK since the EC deemed the UK to have an adequate data protection level, and these adequacy decisions were extended in December 2025, and are now valid until December 27, 2031.

Failure to comply with the requirements of the GDPR and the related national data protection laws of the EU Member States may result in significant monetary fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater, other administrative penalties and a number of criminal offenses for organizations and, in certain cases, their directors and officers, as well as civil liability claims from individuals whose personal data was processed. Data protection authorities from the different EU Member States may still implement certain variations, enforce the GDPR and national data protection laws differently, and introduce additional national regulations and guidelines, which adds to the complexity of processing personal data in the EU.

Furthermore, there are specific requirements relating to processing health data from clinical trials, including those related to public disclosure obligations provided in the EU Clinical Trials Regulation No. 536/2014 ("CTR"), European Medicines Agency ("EMA"), data transparency initiatives and voluntary commitments by industry. Failure to comply with these obligations could lead to government enforcement actions and significant penalties against us, harm to our reputation, and adversely impact our business and operating results.

Additionally, following the UK's withdrawal from the EU and the EEA, companies also have to comply with the UK's data protection laws (including the UK GDPR (as defined in section 3(10) (as supplemented by section 205(4)) of the Data Protection Act 2018 (the "DPA 2018")), the DPA 2018, and related data protection laws in the UK). In June 2025, the UK's Data (Use and Access) Act took effect, which introduces certain relatively minor amendments to the data protection regime in the UK, and therefore creates slight divergences between the EU and UK Data protection regimes. Separate from the fines that can be imposed by the GDPR, the UK regime has the ability to fine up to the greater of £17.5 million or 4% of global turnover.

Companies are subject to specific transfer data sharing and transfer rules under the UK regime which broadly mirror the GDPR rules. We therefore also apply or rely on third parties to implement data sharing and cross-border transfer mechanisms and safeguards, as set out above, in these contexts. On February 2, 2022, the UK Secretary of State laid before the UK Parliament the international data transfer agreement ("IDTA") and the international data transfer addendum to the EC's standard contractual clauses for international data transfers (Addendum) and a document setting out transitional provisions. The IDTA and Addendum came into force on March 21, 2022 and replaced the old SCCs for the purposes of the UK regime.

Regarding transfers from the UK to the EEA, personal data may flow freely since the EEA is deemed to have an adequate data protection level for purposes of the UK regime. With regard to the transfer of personal data from the UK to the United States, the UK government has adopted an adequacy decision for the United States, the UK-US Data Bridge, which came into force on October 12, 2023. The UK-US Data Bridge recognizes the United States as offering an adequate level of data protection where the transfer is to a U.S. company participating in the EU-US Data Privacy Framework and the UK Extension.

The EU has also recently implemented a number of cybersecurity laws, some of which are applicable to the healthcare industry. For example, the Network and Information Security Directive (Directive (EU) 2022/2555) applies to organizations operating in the EU in the healthcare sector and imposes stringent cybersecurity obligations on in-scope organizations, including in relation to supply chain management and incident reporting.

Drug and Biologic Development Process

Regardless of where they are conducted, all clinical trials included in applications for marketing authorization ("MA") for human medicines in the EU/EEA must have been carried out in accordance with EU regulations. This means that clinical trials conducted in the EU/EEA have to comply with EU clinical trial legislation but also that clinical trials conducted outside the EU/EEA have to comply with ethical principles equivalent to those set out in the EEA, including adhering to international good clinical practice and the Declaration of Helsinki. The conduct of clinical trials in the EU is governed by the CTR, which entered into force on January 31, 2022. The CTR replaced the Clinical Trials Directive 2001/20/EC ("Clinical Trials Directive") and introduced a complete overhaul of the existing regulation of clinical trials for medicinal products in the EU.

The EU Clinical Trials Regulation, which replaced the Clinical Trials Directive and has been in force since 2022, aims to harmonize and streamline clinical trial processes across Member States through a centralized application system, the Clinical Trials Information System (CTIS), enabling sponsors to submit a single application for approval. One national regulatory authority, designated as the reporting Member State, leads the validation and evaluation of applications in consultation with other concerned Member States. Applications may be amended and resubmitted if rejected, and approved trials may commence in all relevant Member States, although individual states retain the right to "opt out" in limited circumstances. The Regulation also simplifies safety reporting rules, introduces enhanced transparency requirements such as mandatory submission of trial results summaries to the EU Database. Since January 31, 2023, all initial clinical trial applications must be submitted through CTIS which now serves as the single entry point for clinical trial-related information and data. By January 31, 2025, all ongoing trials approved under the former Clinical Trials Directive must transition to CTIS and comply with the CTR. On July 19, 2023, the EC published guidance for this transition, clarifying that previously assessed documentation will not be reassessed, EU-endorsed templates do not require updates, and site suitability forms are only needed for new trial sites.

Under the CTR, clinical trials must comply with national laws, regulations, and the applicable GCP and GLP standards, and the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use ("ICH") guidelines on Good Clinical Practice, as well as the ethical principles outlined in the Declaration of Helsinki.

During the development of a medicinal product, the EMA and national regulators within the EU provide the opportunity for dialogue and guidance on the development program. At the EMA level, this is usually done in the form of scientific advice, which is given by the Committee for Medicinal Products for Human Use ("CHMP") on the recommendation of the Scientific Advice Working Party. A fee is incurred with each scientific advice procedure, but is significantly reduced for designated orphan medicines. Advice from the EMA is typically provided based on questions concerning, for example, quality (chemistry, manufacturing and controls testing), nonclinical testing and clinical studies, and pharmacovigilance plans and risk-management programs. Advice is not legally binding with regard to any future Marketing Authorization Application ("MAA") of the product concerned.

Drug Marketing Authorization

In the EEA, after completion of all required clinical testing, pharmaceutical products may only be placed on the market after obtaining an MA. To obtain an MA of a drug under EU regulatory systems, an applicant can submit an MAA through, amongst others, a centralized or decentralized procedure, as detailed below.

Centralized Authorization Procedure

The centralized procedure provides for the grant of a single MA that is issued by the EC following the scientific assessment of the application by the EMA that is valid for all EU Member States as well as in the three additional EEA Member States (Norway, Iceland and Liechtenstein). The centralized procedure is compulsory for specific medicinal products, including for medicines developed by means of certain biotechnological processes, products designated as orphan medicinal products, advanced therapy medicinal products (gene therapy, somatic cell therapy or tissue engineered medicines) and medicinal products with a new active substance indicated for the treatment of certain diseases (HIV/AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases). For medicinal products containing a new active substance for indications that do not fall within the mandatory centralized procedure, they are eligible for centralized assessment if they constitute significant therapeutic, scientific or technical innovations or for which the grant of a MA through the centralized procedure would be in the interest of public health at EU level.

Under the centralized procedure, the Committee for Medicinal Products for Human Use ("CHMP") established at the EMA is responsible for the initial assessment of an MAA. The CHMP also oversees the scientific assessment of various post-authorization and maintenance activities, including the assessment of variations or extensions to an existing MA. The standard timeframe for the evaluation of an MAA by the EMA's CHMP is 210 days from receipt of a valid MAA, excluding clock stops for the applicant to provide additional written or oral information in response to questions asked by the CHMP. As a result, the overall process typically takes a year or more, unless the application is eligible for an accelerated assessment. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. Upon request, the CHMP may reduce the time frame to 150 days if the applicant provides sufficient justification for an accelerated assessment. The CHMP will provide a positive opinion regarding the application only if it meets the required standards for quality, safety and efficacy. This opinion is then transmitted to the EC, which has the ultimate authority for granting MA.

Decentralized Authorization Procedure

The decentralized procedure permits companies to file identical MAAs for a medicinal product not falling within the mandatory centralized procedure to the competent authorities in various EU Member States simultaneously if such medicinal product has not received marketing approval in any EU Member State. In this procedure, the reference member state is appointed to lead the scientific review for the agreement with the competent authorities of the other EU Member States concerned by the procedure. A member state may refuse to accept the assessment provided by the reference member state on grounds of a potential serious risk to public health that is defined as a situation where there is a significant probability that a serious hazard resulting from a human medicinal product in the context of its proposed use will affect public health.

Risk Management Plan

All new MAAs must include a Risk Management Plan ("RMP") describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. RMPs are continually modified and updated throughout the lifetime of the medicine as new information

becomes available. An updated RMP must be submitted: (i) at the request of EMA or a national competent authority, or (ii) whenever the risk-management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit-risk profile or as a result of an important pharmacovigilance or risk-minimization milestone being reached. The regulatory authorities may also impose specific obligations as a condition of the MA. All RMPs for centrally authorized products are published by the EMA, subject only to limited redactions.

MA Validity Period

MAs have an initial duration of five years. After these five years, the authorization may subsequently be renewed on the basis of a reevaluation of the risk-benefit balance. Once renewed, the MA is valid for an unlimited period unless the EC or the national competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with only one additional five-year renewal. Applications for renewal must be made to the EMA at least nine months before the five-year period expires.

Any authorization which is not followed by the actual placing of the drug on the EU market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid.

The UK applies a rule, consistent with directly applicable EU law, requiring that nationally approved medicinal products must be placed on the market within three years from the date the marketing authorization is granted. When the Medicines and Healthcare products Regulatory Agency (MHRA) becomes aware that the three-year period is approaching expiry, it will notify the marketing authorization holder in advance that the authorization will cease to be valid if the product is not marketed within the required timeframe. The MHRA provides notification to the marketing authorization holder in both scenarios referenced previously: first, where a product has held a marketing authorization for three years but has not been placed on the market at all; and second, where a product was previously marketed but has subsequently not been placed on the market for a consecutive period of three years. This process ensures compliance with regulatory requirements and maintains the integrity of the national medicines supply.

Following the UK's exit from the EU, the three-year "sunset clause" for centrally authorized products in the UK was effectively reset from the date of conversion (January 1, 2021). This means that any product not placed on the market in Great Britain by early 2024 risked losing its validity unless the appropriate notification was made. The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for managing this process for UK marketing authorizations (PLGB MAs), requiring marketing authorization holders to provide updates on the marketing status of their products. The Windsor Framework agreement establishes that, effective from January 1, 2025, the Medicines and Healthcare products Regulatory Agency (MHRA) will serve as the sole regulatory authority for approving medicines for the entire UK market, encompassing both Northern Ireland and Great Britain. Under the new arrangements, a unified UK-wide authorization process will apply, ensuring that medicines in Northern Ireland are regulated by the MHRA in the same manner as in Great Britain.

On the other hand, for the EU, in the case the drug has been marketed in the UK, the placing on the UK market before the end of the period starting when the UK left the EU on January 31, 2020 and ending on December 31, 2020 (the "Brexit Transition Period") will be taken into account. If, after the end of the Brexit Transition Period, the drug is not placed on any other market of the remaining EU Member States, the three-year period will start running from the last date the drug was placed on the UK market before the end of the Brexit Transition Period.

Advanced Therapy Medicinal Products

In the EU, medicinal products, including ATMPs are subject to extensive pre- and post-market regulation by regulatory authorities at both the EU and national levels. ATMPs comprise gene therapy products, somatic cell therapy products and tissue engineered products, which are genes, cells or tissues that have undergone substantial manipulation and that are administered to human beings in order to cure, diagnose or prevent diseases or regenerate, repair or replace a human tissue. Pursuant to Regulation (EC) No 1394/2007, the Committee for Advanced Therapies ("CAT") is responsible in conjunction with the CHMP for the evaluation of ATMPs. The CHMP and CAT are also responsible for providing guidelines on ATMPs. These guidelines provide additional guidance on the factors that the EMA will consider in relation to the development and evaluation of ATMPs and include, among other things, the preclinical studies required to characterize ATMPs. Although such guidelines are not legally binding, compliance with them is often necessary to gain and maintain approval for product candidates.

In addition to the mandatory RMP, the holder of a MA for an ATMP must put in place and maintain a system to ensure that each individual product and its starting and raw materials, including all substances coming into contact with the cells or tissues it may contain, can be traced through the sourcing, manufacturing, packaging, storage, transport and delivery to the relevant healthcare institution where the product is used.

Exceptional Circumstances and Conditional Approval

Similar to accelerated approval regulations in the United States, conditional MAs can be granted in the EU in exceptional circumstances. A conditional MA can be granted for medicinal products where, although comprehensive clinical data referring to the safety and efficacy of the medicinal product have not been supplied, a number of criteria are fulfilled: (i) the benefit/risk balance of the product is positive, (ii) it is likely that the applicant will be in a position to provide the comprehensive clinical data, (iii) unmet medical needs will be fulfilled by the grant of the MA and (iv) the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required. Once a conditional MA has been granted, the MA holder must fulfil specific obligations within defined timelines. A conditional MA is valid for one year and must be renewed annually, but it can be converted into a standard MA once the MA holder fulfils the obligations imposed and the complete data confirm that the medicine's benefits continue to outweigh its risks.

Data and Market Exclusivity

Under EU pharmaceutical law, reference medicinal products are granted 8 years of data exclusivity, during which generic and biosimilar manufacturers cannot rely on the originator's non-clinical and clinical data for regulatory approval. This is followed by 2 years of marketing exclusivity, preventing generics and biosimilars from entering the market for a total of 10 years. If, within the first 8 years, the reference product is approved for a new indication that provides significant clinical benefit, the exclusivity period may be extended to 11 years. These rules ensure that generics and biosimilars cannot seek approval or enter the market until the exclusivity periods have expired, balancing incentives for innovation with future market competition.

A reference medicinal product for data and marketing exclusivity typically contains a new active substance and requires a full dossier, including pharmaceutical, non-clinical, and clinical trial data, for approval. The European Medicines Agency (EMA), based on the scientific assessment and opinion of its Committee for Medicinal Products for Human Use (CHMP), determines whether a product contains a new active substance. Data and marketing exclusivity do not prevent other companies from generating their own data through independent development to demonstrate the safety, quality, and efficacy of their own products.

Recent reforms introduced through the EU Pharma Package and the proposed Biotech Act bring significant changes, including streamlined authorization procedures, enhanced measures for access and affordability, stricter management of medicine shortages, strengthened post-market surveillance, and new requirements addressing environmental and ethical considerations. These initiatives are designed to modernize and harmonize medicines regulation, facilitate patient access to innovative therapies, and provide robust oversight of emerging technologies across the EU.

The legislative process for the EU Pharma Package began with the European Commission's proposal in April 2023, followed by the development of positions by the European Parliament and the Council. This culminated in Trilogue negotiations, with a political agreement reached in December 2025. The agreed text now awaits formal adoption by both the Parliament and Council, after which it will be published in the Official Journal of the EU. The new Directive and Regulation will then enter into force following a transition period of 18 to 36 months, ultimately modernizing EU pharmaceutical law to better support innovation, access, and supply. Under the agreed EU Pharma Package, companies launching new medicines will benefit from eight years of data protection and one year of market exclusivity, with a possible additional year for innovative products meeting specific criteria.

Pediatric Development

In the EU, companies developing a new medicinal product are obligated to study their product in children and must therefore submit a PIP together with a request for agreement to the EMA. The EMA issues a decision on the PIP based on an opinion of the EMA's Pediatric Committee. Companies must conduct pediatric clinical trials in accordance with the PIP approved by the EMA, unless a deferral (e.g. until enough information to demonstrate its effectiveness and safety in adults is available) or waiver (e.g. because the relevant disease or condition occurs only in

adults) has been granted by the EMA. The MAA for the medicinal product must include the results of all pediatric clinical trials performed and details of all information collected in compliance with the approved PIP, unless a waiver or a deferral has been granted, in which case the pediatric clinical trials may be completed at a later date. Medicinal products that are granted an MA on the basis of the pediatric clinical trials conducted in accordance with the approved PIP are eligible for a six-month extension of the protection under a supplementary protection certificate (if any is in effect at the time of approval), or, in the case of orphan medicinal products, a two-year extension of the orphan market exclusivity. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the approved PIP are developed and submitted. An approved PIP is also required when a MA holder wants to add a new indication, medicinal form or route of administration for a medicine that is already authorized and covered by intellectual property rights.

In the UK, the MHRA has established a closely aligned process, frequently accepting agreed EU PIPs and decisions to streamline UK submissions. However, the MHRA maintains UK-specific requirements, such as the need for a UK PIP for new medicines.

Post-Approval Regulation

Similar to the United States, both MA holders and manufacturers of medicinal products in the EU are subject to comprehensive regulatory oversight by the EMA, the EC and/or the competent regulatory authorities of the EU Member States. The regulatory oversight covers every stage of the authorization process, from initial grant of an approval to ongoing monitoring of compliance with EU cGMPs, manufacturing authorizations, pharmacovigilance rules and requirements governing advertising, promotion, sale, and distribution, recordkeeping, importing, and exporting of medicinal products.

These regulatory requirements are designed to ensure that the safety, quality, and efficacy standards of medicinal products are consistently maintained throughout their lifecycle. Failure by us or by any of our third-party partners, including suppliers, manufacturers and distributors to comply with EU laws and the related national laws of individual EU Member States governing the conduct of clinical trials, manufacturing approval, MA of medicinal products and marketing of such products, both before and after grant of MA, statutory health insurance, bribery and anti-corruption or other applicable regulatory requirements may result in administrative, civil or criminal sanctions. These include delays or refusal to authorize the conduct of clinical trials or to grant MA, product withdrawals and recalls, product seizures, withdrawal or suspension of authorizations, restrictions on regulated activities such as production, distribution, manufacturing or clinical trials, operating restrictions, and financial penalties.

The holder of an MA for a medicinal product must also comply with EU pharmacovigilance legislation and its related regulations and guidelines, which entail many requirements for conducting pharmacovigilance, or the assessment and monitoring of the safety of medicinal products.

These pharmacovigilance rules require holders of MAs the obligation to develop a system capable of collecting, collating, assessing, and reporting post-authorization data to monitor the ongoing risks and benefits of marketed medicinal products, as well as the requirement to conduct additional clinical studies or post-authorization safety or efficacy studies to address uncertainties about the risk-benefit balance, or to measure the effectiveness of risk-management measures. Such post-authorization measures may be time-consuming and expensive and could impact our profitability. MA holders must establish and maintain a pharmacovigilance system designed to monitor the safety of authorized medicinal products and detect any change to their risk-benefit balance and appoint an individual qualified person for pharmacovigilance, who is responsible for the oversight of that system. Key obligations include expedited reporting of unexpected serious adverse reactions and submission of Periodic Safety Update Reports ("PSURs") in relation to medicinal products for which they hold MAs. The EMA reviews PSURs for medicinal products authorized through the centralized procedure. If the EMA, based on the scientific assessment conducted by its advisory committees, determines that the risk-benefit profile of a product has changed, it may issue an opinion recommending suspension, withdrawal, or variation of the existing MA. The scientific opinion must be ratified by the EC in a legally binding decision. If the MA holder fails to meet the obligations set out in the EC's decision, the validity of the MA may be compromised. For centrally authorized products, non-compliance with pharmacovigilance requirements can result in regulatory sanctions, including financial penalties imposed by the EC.

More generally, non-compliance with pharmacovigilance obligations can lead to the variation, suspension or withdrawal of the MA for the product or imposition of financial penalties or other enforcement measures.

The manufacturing process for pharmaceutical products in the EU is highly regulated and regulators may shut down manufacturing facilities that they believe do not comply with regulations. Manufacturing requires a manufacturing authorization, and the manufacturing authorization holder must comply with various requirements set out in the applicable EU laws, regulations and guidance, including Directive 2001/83/EC, Directive 2003/94/EC (repealed by Directive 2017/1572 on January 31, 2022), Regulation (EC) No 726/2004 and the European Commission Guidelines for Good Manufacturing Practice ("GMP"). These requirements include compliance with EU cGMP standards when manufacturing pharmaceutical products and active pharmaceutical ingredients, including the manufacture of active pharmaceutical ingredients outside of the EU with the intention to import the active pharmaceutical ingredients into the EU. Amendments or replacements of at least Directive 2001/83/EC and Regulation (EC) No 726/2004 are part of the reform proposal for European pharmaceutical legislation. Similarly, the distribution of pharmaceutical products into and within the EU is subject to compliance with the applicable EU laws, regulations and guidelines, including the requirement to hold appropriate authorizations for distribution granted by the competent authorities of the EU Member States. The manufacturer or importer must have a qualified person who is responsible for certifying that each batch of product has been manufactured in accordance with GMP and the terms of a marketing authorization or clinical trial authorization, before releasing the product for commercial distribution in the EU or for use in a clinical trial. Manufacturing facilities are subject to periodic inspections by the competent authorities for compliance with GMP.

Advertising and Promotion Regulations

The advertising and promotion of our products is also subject to EU laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. In addition, other national legislation of individual EU Member States may apply to the advertising and promotion of medicinal products and may differ from one country to another. These laws require that promotional materials and advertising in relation to medicinal products comply with the product's SmPC as approved by the competent regulatory authorities. The SmPC is the document that provides information to physicians concerning the safe and effective use of the medicinal product. It forms an intrinsic and integral part of the MA granted for the medicinal product. Promotion of a medicinal product that does not comply with the SmPC is considered to constitute off-label promotion. All advertising and promotional activities for the product must be consistent with the approved SmPC and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription-only medicines is also prohibited in the EU. Violations of the rules governing the promotion of medicinal products in the EU could be penalized by administrative measures, fines and imprisonment. These laws may further limit or restrict the advertising and promotion of our products to the general public and may also impose limitations on its promotional activities with healthcare professionals.

EU regulation with regards to dispensing, sale and purchase of medicines has generally been preserved in the UK following Brexit, through the Human Medicines Regulations 2012. However, organizations wishing to sell medicines online need to register with the MHRA. Following Brexit, the requirements to display the common logo no longer apply to UK-based online sellers, except for those established in Northern Ireland.

Anti-Corruption Legislation

In the EU, interactions between pharmaceutical companies and physicians are also governed by strict laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct both at EU level and in the individual EU Member States. The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the EU. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of the EU Member States. Violation of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain EU Member States also must be publicly disclosed. Moreover, agreements with physicians must often be the subject of prior notification and approval by the physician's employer, his/her regulatory professional organization, and/or the competent authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes, or professional codes of conduct, applicable in the individual EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

In the UK, the pharmaceutical sector is recognized as being particularly vulnerable to corrupt practices, some of which fall within the scope of the Bribery Act 2010. Due to the Bribery Act 2010's far-reaching territorial application, the potential penalized act does not have to occur in the UK to become within its scope. If the act or omission does not take place in the UK, but the person's act or omission would constitute an offense if carried out there and the person has a close connection with the UK, an offense will still have been committed.

The Bribery Act 2010 is comprised of four offenses that cover (i) individuals, companies and partnerships that give, promise or offer bribes, (ii) individuals, companies and partnerships that request, agree to receive or accept bribes, (iii) individuals, companies and partnerships that bribe foreign public officials, and (iv) companies and partnerships that fail to prevent persons acting on their behalf from paying bribes. The penalties imposed under the Bribery Act 2010 depend on the offence committed, harm and culpability and penalties range from unlimited fines to imprisonment for a maximum term of ten years and in some cases both.

Regulations in the UK and Other Markets

The UK formally left the EU on January 31, 2020 and EU laws now only apply to the UK in respect of Northern Ireland as laid out in the Protocol on Ireland and Northern Ireland and as amended by the Windsor Framework sets out a long-term set of arrangements for the supply of medicines into Northern Ireland. The EU and the UK agreed on a trade and cooperation agreement ("TCA"), which includes provisions affecting the life sciences sector (including on customs and tariffs). There are some specific provisions concerning pharmaceuticals, including the mutual recognition of GMP, inspections of manufacturing facilities for medicinal products and GMP issued documents. The TCA does not, however, contain wholesale mutual recognition of UK and EU pharmaceutical regulations and product standards.

The UK government has adopted the Medicines and Medical Devices Act 2021 (the "MMDA") to enable the UK's regulatory frameworks to be updated following the UK's departure from the EU. The MMDA introduces regulation-making, delegated powers covering the fields of human medicines, clinical trials of human medicines, veterinary medicines and medical devices. The MHRA has since been consulting on future regulations for medicines and medical devices in the UK.

For other countries outside of the EU, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials must be conducted in accordance with GCPs and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension of clinical trials, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Corporate Information

We were formed as a Delaware corporation in 1992 under the name "Nuvelo, Inc." and subsequently, in 2009, we completed a business combination with ARCA biopharma, Inc. On August 29, 2024, we completed the Merger with Pre-Merger Oruka and changed our name from "ARCA biopharma, Inc." to "Oruka Therapeutics, Inc." Our corporate headquarters are located at 855 Oak Grove Avenue, Suite 100, Menlo Park, California 94025. The telephone number at our corporate headquarters is (650) 606-7910. Our corporate website address is *www.orukatx.com*. We do not incorporate information contained on, or accessible through, our website into this Annual Report on Form 10-K, and you should not consider it part of this Annual Report.

Employees and Human Capital Resources

As of December 31, 2025 we had 68 full-time employees of which 51 employees were in research and development and the remaining 17 employees worked in finance, legal, business development, human resources, and administrative support. All our full-time employees are located in the United States. We also engage temporary employees and consultants to augment our existing workforce. None of our employees are represented by a labor union or covered under a collective bargaining agreement. We consider our relationship with our employees to be good.

We recognize that attracting, motivating, and retaining talent at all levels is vital to continuing our success. We invest in our employees through high-quality benefits, professional development opportunities, and various health and wellness initiatives and offer competitive compensation packages (base salary and incentive plans), ensuring fairness in internal compensation practices. The principal purposes of our incentive plans (bonus and equity) are to align with the long-term interests of our stakeholders and stockholders.

Item 1A. Risk Factors.

Risk Factors Summary

We are subject to a number of risks that could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this Form 10-K and those we may make from time to time. 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. In addition, some of the factors, events and contingencies discussed below may have occurred in the past, but the disclosures below are not representations as to whether or not the factors, events or contingencies have occurred in the past and instead reflect our beliefs and opinions as to the factors, events, or contingencies that could materially and adversely affect us in the future.

The following summary is not exhaustive and is qualified by reference to the full set of risk factors set forth in Item 1A "Risk Factors" of this Form 10-K. Please carefully consider all the information in this Form 10-K, including the full set of risks set forth in the "Risk Factors" section and in our other filings with the U.S. Securities and Exchange Commission ("SEC"), before making an investment decision regarding the Company.

Risks Related to Our Financial Condition and Capital Requirements

- We are a clinical stage biopharmaceutical company with a limited operating history on which to assess our business. Our clinical trials remain ongoing and we 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, Regulatory Approval and Commercialization

- 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. We may not achieve our projected development goals in the time frames we announce and expect, or at all.
- We face competition from entities that have developed or may develop programs for the diseases addressed by our product candidates.

Risks Related to Government Regulations

- We may not be able to meet requirements for the chemistry, manufacturing and control of our programs.
- The U.S. 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. Moreover, even if we obtain regulatory approval, we will be subject to ongoing regulatory obligations.

Risks Related to Our Intellectual Property

- Our ability to obtain and protect our patents and other proprietary rights is uncertain and we may fail in obtaining or maintaining necessary rights to our programs.
- We may become subject to claims challenging the inventorship or ownership of our intellectual property and may be subject to patent infringement claims or may need to file such claims.
- Our technology licensed from 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. Our business could be negatively impacted if we are unable to maintain these arrangements or if these arrangements are not successful, for example, if such third parties fail to carry out their contractual duties.
- Our third-party manufacturing partners and manufacturing sites may fail to perform adequately in their efforts to support the manufacture of our product candidates and we may need to switch or create third-party manufacturer redundancies.

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

- 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 business is dependent on key personnel, and we may be harmed if we cannot recruit and retain highly qualified personnel to successfully implement our business strategies.
- Our business could be adversely affected by macroeconomic or geopolitical conditions.
- Future sales and issuances of equity and debt could result in additional dilution to our stockholders and could cause our stock price to decline.
- Future sales of shares, or the anticipation of such sales, by existing stockholders could cause our stock price to decline.

Risk Factors

Risks Related to Our Financial Condition and Capital Requirements

We are a clinical stage biopharmaceutical company with a limited operating history on which to assess our business; our clinical trials are ongoing, we have no products approved for commercial sale, we 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 clinical 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 we could exhaust our available financial resources sooner than we currently anticipate. We have devoted substantially all of our financial resources to identifying, acquiring, and developing our product candidates, organizing and staffing our company, and providing general and administrative support for our operations.

Additional capital may not be available in sufficient amounts or on reasonable terms, if at all. The current market environment for small and midcap biotechnology companies and broader macroeconomic factors may preclude us from successfully raising additional capital on the timeline we require. For example, escalating geopolitical tensions, elevated interest rates, and economic and regulatory uncertainty have caused market volatility. Such volatility can have an adverse effect on the ability to raise capital, particularly in the biotechnology and biopharmaceutical industries. In addition, it may be difficult for us to raise additional capital if we experience any issues that delay or prevent the regulatory approval or our ability to commercialize any of our product candidates.

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 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 approved markets, and our ability to achieve sufficient market acceptance, pricing, coverage and adequate reimbursement from third-party payors, and adequate market share for our products. However, even if we obtain adequate market share for our products, 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 clinical development of our product candidates, including advancing our product candidates into larger, more expensive trials;
- progress our chemistry, manufacturing and control development, registration, and validation, including the manufacture of our product candidates by third parties, including increasing volumes manufactured by third parties;
- continue efforts to discover and develop new product candidates, including initiating preclinical studies or clinical trials;
- seek regulatory and marketing approvals and reimbursement for our product candidates;
- establish a sales, marketing, and distribution infrastructure to commercialize any products for which we 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 product candidates such as safety issues, manufacturing delays, clinical trial delays, longer follow-up for planned studies or trials, additional major studies or trials, or supportive trials necessary to support marketing approval.

If we are unable to raise additional capital when required or on acceptable terms, we may be required to curtail our product development activities and other activities commensurate with the magnitude of the shortfall and our product development activities may cease altogether, which could materially harm our business, financial condition, and results of operations. To the extent that the costs of our activities exceed our current estimates and we are unable to raise sufficient additional capital to cover such costs, we will need to reduce operating expenses, sell assets, enter into strategic transactions, or effect a combination of the above. No assurance can be given that we will be able to enter into any of such transactions on acceptable terms, if at all. Any of the following events could have a material adverse effect on our business, operating results, and prospects:

- a delay, scaling back, or discontinuation of the development or commercialization of our product candidates;
- seeking strategic partnerships, or amending 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;
- disposal of technology assets, or the relinquishing or licensing of assets on unfavorable terms, of our rights to technologies or any of our product candidates that we otherwise would seek to develop or commercialize ourselves;
- pursuing the sale of the company to a third party at a price that may result in a loss on investment for our stockholders; or
- filing for bankruptcy or ceasing operations altogether.

Even if we are successful in raising additional capital, the amount of capital we raise may be limited or restricted due to investor demand, market conditions, or other factors.

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. For example, in September 2024, we entered into a Securities Purchase Agreement with certain institutional and accredited investors, whereby the investors purchased an aggregate of 5,600,000 shares of common stock, 2,439 shares of Series A Preferred Stock and pre-funded warrants to purchase an aggregate of 680,000 shares of common stock and in November 2024, each outstanding share of Series A Preferred Stock converted into 1,000 shares of common stock. Furthermore, in September 2025, we entered into a Securities Purchase Agreement with certain institutional and accredited investors, whereby the investors purchased an aggregate of 10,933,405 shares of our common stock and pre-funded warrants to purchase 1,066,666 shares of common stock. In addition, in October 2025, we entered into a sales agreement with TD Securities (USA) LLC acting as our sales agent pursuant to which we may issue and sell shares of our common stock from time to time through an at-the-market equity offering program, for aggregate gross proceeds of up to $200.0 million, under which we have sold shares of our common stock resulting in net proceeds of $38.9 million as of March 2026.

Moreover, 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.

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 our product candidates.

The development and commercialization of drugs is highly competitive. If approved, our product candidates will face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration. 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 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 may develop programs and processes that compete with ours. 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 may be reduced or eliminated if competing products are safer, more effective, have a more attractive dosing profile or presentation, or are less expensive than our products, or if biosimilars enter the market and achieve broader or more rapid market acceptance than our products.

Our product candidates 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 expect it will be many years before we can obtain regulatory approval for and commercialize any product candidate, if ever. 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 events affecting our product development timeline, including the following:

- Our clinical trials may fail to show safety or efficacy, show meaningful improvement in efficacy or convenience compared to competitors, produce negative or inconclusive results, or our product candidates may have undesirable side effects or unexpected characteristics. We may decide, or regulators may require additional preclinical studies or clinical trials or we may decide to abandon a product development program altogether.
- The supply or quality of our clinical trial materials or other materials necessary to conduct clinical trials of our product candidates may be insufficient, unsafe or inadequate.
- Regulators, Institutional Review Boards ("IRBs"), the FDA, or ethics committees may not authorize us or our investigators to commence or conduct a clinical trial at one or more prospective trial sites; or may require that we or our investigators materially modify, 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.
- We may fail to establish an appropriate safety profile for a product candidate based on clinical or preclinical data as well as data emerging from other therapies in the same class as our product candidates.
- 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.

- Trial conduct or data analysis errors may occur, including, but not limited to, failure by investigators or participants to adhere to the study protocol or data entry and/or labeling errors.
- We may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and/or contract research organizations.
- Our third-party contractors or clinical trial sites 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 and could potentially complicate the analysis of data or affect our product development timeline.
- 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.
- The FDA or other regulatory authorities may require us to submit additional data or impose other requirements and our product development timeline may be adversely affected.
- 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 our clinical trials do not produce favorable results, our ability to obtain regulatory approval for our product candidates will be adversely impacted. Moreover, the combined data from our trials may be 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 outside of the United States, including the European Union ("EU").

In addition, in part due to the competitive landscape for immunology and inflammation (commonly referred to as "I&I") indications, we may also face increased 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' 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 and have an adverse effect on our business and operations.

We are substantially dependent on the success of our two most advanced programs, ORKA-001 and ORKA-002, and our 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 the majority of our efforts and financial resources into the research and development of these programs. Our Phase 1 clinical trial of ORKA-001 in healthy volunteers is fully enrolled and is ongoing for purposes of continued patient follow-up and data collection, and remains blinded. Our Phase 2a clinical trial of ORKA-001 in patients with moderate-to-severe psoriasis ("PsO") remains ongoing and we commenced dosing in a dose-ranging Phase 2b trial of ORKA-001 in moderate-to-severe PsO in the fourth quarter of 2025.

Our Phase 1 clinical trial of ORKA-002 in healthy volunteers is fully enrolled and remains ongoing for purposes of continued patient follow-up and data collection, and remains blinded. In addition, we expect to commence a Phase 2 clinical trial of ORKA-002 in patients with moderate-to-severe PsO in the first half of 2026 and plan to initiate a Phase 2 clinical trial of ORKA-002 in hidradenitis suppurativa ("HS") in the second half of 2026.

Currently, we believe that the success of our programs is dependent on our product candidates demonstrating a longer half-life in humans than monoclonal antibodies 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. To the extent we do not observe this extended half-life, it would significantly and adversely affect the clinical and commercial potential of our product candidates.

If we do not achieve our projected development goals in the time frames we announce or 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 announce the timing of the anticipated accomplishment of various scientific, clinical, regulatory, or other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of scientific studies and clinical trials, such as the expected timing of our clinical trials in our target indications, anticipated data analysis, and the data results from our clinical trials, as well as the submission of regulatory filings. 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 or the timing of the milestones as publicly announced, 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 on terms less than desirable, 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 are delivering and expect to continue to deliver, our product candidates via a drug delivery device, such as pre-filled syringe, an injector, or other delivery system. We currently expect to utilize drug delivery devices authorized for marketing under clearances of approvals held by third parties. Where approval of a drug product and device is sought under a single application, the increased complexity of the review process may delay approval. 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. In addition, some drug delivery

devices are provided by single-source 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 for our products, we may also be dependent on those third-party companies continuing to maintain such approvals or clearances, if required, for their drug delivery devices once they have been received. Moreover, 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. 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 lead programs is unproven, and we may not be successful in our efforts to build a pipeline of programs with commercial value.

We have worked with Paragon to leverage clinically validated mechanisms of action and incorporate advanced antibody engineering to optimize half-life and other properties designed to overcome limitations of existing therapies. We have entered into antibody discovery and option agreements (the "Option Agreements") with Paragon Therapeutics, Inc. ("Paragon") and Paruka Holding LLC to facilitate the discovery and development of certain research programs with respect to which we have signed a license agreement with Paragon. Our two most advanced programs, ORKA-001 and ORKA-002, are licensed from Paragon and 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-lives and exposure profiles of our programs compared to currently approved products are 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. In addition, programs using half-life extension technologies may demonstrate different chemical and pharmacological properties in human participants than they do in laboratory studies or preclinical studies, including the inability to demonstrate the same chemical and pharmacological properties in humans or the potential interaction with human biological systems in unforeseen, ineffective, or harmful ways.

If the products resulting from the research programs with respect to which we have signed license agreements with Paragon 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.

In addition, we may in the future seek to discover and develop programs that are based on novel targets and in the 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.

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. Further, 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.

We do not know whether any clinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market any of our product candidates. Clinical testing can take many years to complete, and its outcome is inherently uncertain. 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. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials and results in one indication may not be predictive of results to be expected for the same product candidate in another indication. We plan to use the data from our current trials of our ORKA-001 and ORKA-002 programs

to support further trials in PsO, HS, and potentially other I&I indications. However, differences between early-stage clinical trials and later-stage clinical trials, including differences in trial design, among other things, make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unfavorable safety profiles, notwithstanding promising results in earlier trials. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of such product candidates. In addition, we rely on clinical trial site staff to measure psoriasis area severity index scores (PASI scores) and participants to provide feedback on measures such as measures of quality of life, which may involve subjective interpretation and variability, although training and standardized measurements will be provided to individuals in order to minimize subjectivity. Moreover, these measures can be influenced by factors outside of our control, and can vary widely within a clinical trial.

We cannot be sure that the FDA, or comparable foreign regulatory authority, as applicable, will agree with our clinical development plan. We cannot assure that the submission of an Investigational New Drug (IND) application, clinical trial application, 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. If the FDA and/or comparable foreign regulatory authority requires us to materially modify our proposed trial designs, conduct additional trials or enroll additional participants, our development timelines may be delayed. Moreover, even if these trials begin, issues may arise that could suspend or terminate such clinical trials, including but not limited to delays or difficulties recruiting trial patients, delays or difficulties obtaining required IRB or ethics committee approval at each clinical trial site, failure by third parties or us to adhere to clinical trial protocols or failure to perform in accordance with current Good Clinical Practice or applicable regulatory requirements, or delays in reaching a consensus with regulatory authorities on trial design or implementation of a clinical trial, or our third party vendors not satisfying their obligations to us.

We could also encounter delays if a clinical trial is required to be materially modified or suspended or terminated by us, the IRBs, by a Data Safety Monitoring Board, if any, or by the FDA or comparable foreign regulatory authorities. Such authorities may suspend, put on clinical hold, or terminate a clinical trial due to a number of factors, including not aligning with or supporting our clinical trial designs or our 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, 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.

Our clinical development activities could be delayed or otherwise adversely affected if we encounter difficulties enrolling and maintaining participants in our current and future clinical trials. We depend on the successful completion of clinical trials for our product candidates.

Our inability to enroll and maintain a sufficient number of participants who remain in a trial until conclusion 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. The enrollment of participants in current or future trials for any of our programs will depend on many factors, including if participants choose to enroll in our 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, we may have difficulty maintaining participants in such clinical trials.

Preliminary, "topline", or interim data from our clinical trials may change and are subject to audit and verification procedures, and should be viewed with caution until the final data are available. Our interpretation of such data is based on assumptions that may evolve as additional data become available, which could result in changes to conclusions regarding the safety, efficacy, timing, or likelihood of success of our clinical development programs.

From time to time, we may publicly disclose preliminary or topline data from our preclinical studies and clinical trials that 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 may 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 and our conclusions may change or be qualified as additional data are received, fully evaluated, and subjected to audit and verification procedures.

We may also publicly disclose interim data from our preclinical studies and clinical trials. Such interim data are inherently preliminary and subject to the risk that one or more of the clinical outcomes may change as participant enrollment continues, additional data become available, as participants from our clinical trials pursue other treatments, or further analyses are conducted. In addition, third parties, 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 perceived value of the particular product candidate, the approvability or commercialization of the particular product candidate, and our company and our business in general. In addition, others may not agree with what we determine is material or otherwise appropriate information to include in our public disclosure of a particular preclinical study or clinical trial.

If the preliminary, topline, or interim data that we report differ from actual results, or if final data or data from later stage clinical trials do not produce favorable results, 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, undesirable side effects, or patient intolerance not seen in our preclinical studies or earlier clinical trials, 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. We do not know whether any clinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market any of our product candidates.

Results of our clinical trials could reveal an unacceptable severity and prevalence of side effects or patient intolerance, adverse events, or unexpected characteristics, and any of these occurrences could harm our business, financial condition, results of operations and prospects significantly. If significant adverse events or other side effects are observed in any of our clinical trials, we may have difficulty recruiting participants to such trials, participants may drop out of the trials, or we may have to suspend, materially modify or 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 or require the material modification of any clinical trials of any program or require that we repeat or conduct additional clinical trials at any time for various reasons, including safety and health risks or exposure to adverse side effects.

Even if 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. 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. In addition, an extended half-life could prolong the duration of undesirable side effects, which could also affect our clinical trials or inhibit market acceptance.

In addition, even if we successfully advance our 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 and potentially over an extended period of use. 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 or longer.

If any of the foregoing events occur or if one or more of our product candidates prove to be unsafe, our 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.

We are initially focused on our most advanced programs, ORKA-001 and ORKA-002, and 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 be in a position where we may have to relinquish valuable rights to that product candidate through collaboration, licensing or other arrangements in cases in which we would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. We may never receive approval to market and commercialize any product candidate.

Any approved products resulting from our programs 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, it may not gain market acceptance among physicians, patients, third-party payors or others in the medical community. Market acceptance of our product candidates will depend on many factors, including factors that are not within our control. Market participants with 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. Moreover, an extended half-life may make it more difficult for patients to change treatments and there may be a perception that half-life extension could exacerbate side effects, each of which may adversely affect our ability to gain market acceptance. Further, we may not generate or derive sufficient revenue from a product candidate and may not become or remain profitable if such product candidate is approved, but does not achieve an adequate level of acceptance.

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 PsO, HS, 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, concurrent clinical trials across multiple programs may compete for the enrollment of participants. In addition, the approval of multiple product candidates for the same indication could intensify market competition and limit our future revenues.

We are conducting, and may conduct in the future, clinical trials for programs at sites outside the United States, subjecting us to additional risks that may delay or adversely affect our product development timelines.

We are currently conducting clinical trials outside the United States and may continue to do so in the future. Conducting clinical trials outside the United States may expose us to additional operational and regulatory risks, including differing regulatory standards and review timelines and increased complexity in ensuring compliance with applicable laws and data protection requirements. 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. 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 impose additional conditions, such as requiring 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 United States presents additional risks that may delay completion of our clinical trials. These risks include requirements for local ethics approvals, challenges in monitoring trial conduct and data integrity across jurisdictions, including the potential failure of investigators or enrolled participants in foreign countries to adhere to clinical protocol 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, such as local privacy restrictions, on data generated from the clinical trial, and diminished protection of intellectual property in some countries. Operations in foreign jurisdictions are subject to additional risks, including dependence on third party manufacturers or suppliers outside of the United States, as well as political and economic risks relevant to foreign countries.

Risks Related to Government and Regulatory Matters

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

The lengthy regulatory approval process as well as the unpredictability of clinical trial results may result in our failing to obtain or be delayed in obtaining approval to market our product candidates, which would significantly harm our business, results of operations and prospects. Before obtaining regulatory approvals for the commercial sale of our product candidates, 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. In addition, 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. Of the large number of drugs in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. Approval may never be obtained and the approval process can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. While there are several approved products and product candidates in later stages of development for the treatment of PsO and for the treatment of HS, our programs incorporate advanced antibody engineering to optimize the half-life and formulation of antibodies, and to date, no such antibody has been approved by the FDA for the treatment of PsO or for HS.

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 failure to demonstrate that a product candidate's benefits outweigh safety risks; regulatory authorities may disagree with our interpretation of clinical data or the data collected may not be acceptable or sufficient to support submission; or the results may not meet the level of statistical significance required for approval by the relevant regulatory authorities or otherwise considered insufficient by the FDA or comparable foreign regulatory authorities. Regulatory authorities may require the addition of labeling statements, such as a black box warning or other warnings or contraindications that could diminish the usage of the product or otherwise limit the commercial success of the affected product.

Moreover, 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 may 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, among other things, 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 in larger quantities as we move forward in our development programs, and demonstrating that our drug products meet stability requirements. As noted above, we may deliver our product candidates via a drug delivery device, which also requires us to meet certain chemistry, manufacturing and control requirements set forth by the FDA and other foreign regulatory authorities. 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 our clinical trials or getting our product candidates approved by regulatory authorities.

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

The Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act (the "ACA"), includes a subtitle called the Biologics Price Competition and Innovation Act (the "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 our product candidates receive regulatory approval, we will remain subject to extensive ongoing regulatory obligations and continued regulatory review, which could result in restrictions on the use of the products, significant additional expenses, and penalties if we fail to comply with regulatory requirements or experience unanticipated issues with our product candidates.

If any of our product candidates receive regulatory approval, we will remain subject to ongoing regulatory requirements imposed by the FDA and comparable foreign authorities. These requirements may include post-approval safety and pharmacovigilance reporting, product labeling restrictions or warnings, risk management requirements such as a Risk Evaluation and Mitigation Strategy ("REMS"), post-marketing commitments or additional studies to further assess safety, efficacy, or real-world use, as well as compliance with applicable manufacturing and quality system regulations.

Regulatory authorities may also conduct periodic inspections of our manufacturing facilities or those of our third-party manufacturers and may take enforcement action if we or such third parties fail to comply with applicable regulatory requirements or if safety, quality, or manufacturing issues arise. Such actions could include labeling changes, restrictions on use or distribution, clinical holds, recalls or withdrawal of products, warning or untitled letters, fines, penalties, or other enforcement measures. Failure to comply with these ongoing obligations, or the emergence of unexpected safety or quality issues after commercialization, could result in significant additional costs, limit our ability to commercialize, and may materially harm our business.

Disruptions or changes at the FDA, the SEC and other government agencies and regulatory authorities could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review regulatory filings and our ability to commence clinical trials can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, statutory, regulatory and policy changes, disruptions caused by government shutdowns and public health crises. There have been mass layoffs of federal government employees since the start of the Trump administration in January 2025, the full impact of which is unclear at this time. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC, and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Furthermore, the Trump administration has made

and is expected to continue to make changes in the leadership of various U.S. federal regulatory agencies and changes to U.S. federal government policy that have led to, in some cases, legal challenges and uncertainty around the funding, functioning and policy priorities of the U.S. federal regulatory agencies, including the FDA.

Disruptions at the FDA and other agencies or comparable foreign regulatory authorities, may also slow the time necessary for the review and approval of applications for clinical trial or marketing authorization, which would adversely affect our business. For example, in recent years, the U.S. government has experienced shut downs and funding lapses, during which time certain regulatory agencies, such as the FDA and the SEC, furloughed critical employees and stopped critical activities. Additionally, action by the Trump administration to limit federal agency budgets or personnel may result in reductions to the FDA's budget, employees, and operations, which may lead to slower response times and longer review periods, potentially affecting our ability to progress development of our product candidates or obtain regulatory approval for our product candidates. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

We are unable to predict the extent to which the Trump administration may impose or seek to impose leadership or policy changes at the FDA or changes to rules and policies impacting our business and operations. It is unclear how these executive actions or other potential actions by the federal government will impact the FDA or other regulatory authorities that oversee our business. Government proposals to reduce or eliminate budgetary deficits may include reduced allocations to the FDA and other related government agencies. These budgetary pressures may reduce the FDA's ability to perform its responsibilities, which could result in delays in our clinical trial timelines. If a significant reduction in the FDA's workforce occurs, the FDA's budget is significantly reduced or a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions or take other actions critical to the development or manufacturing of our product candidates, which could have a material adverse effect on our business.

If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

We may face difficulties from legislative or regulatory reform measures.

We may be faced with additional or changing regulatory and governmental regulations that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, the Trump administration has discussed several changes to the reach and oversight of the FDA, which could affect its relationship with the pharmaceutical industry, transparency in decision making and ultimately the cost and availability of prescription drugs. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

The price of pharmaceuticals has been a topic of considerable public discussion that could lead to price controls or other price-limiting strategies by third-party payors that have the effect of lowering payment and reimbursement rates for drugs or otherwise making the commercialization of pharmaceuticals less profitable. Many federal and state legislatures have considered, and adopted, healthcare policies intended to curb rising healthcare costs, such as the Inflation Reduction Act ("IRA"). These cost-containment measures may include, among other measures: requirements for pharmaceutical companies to negotiate prescription drug prices with government healthcare programs; controls on government-funded reimbursement for drugs; new or increased requirements to pay prescription drug rebates to government healthcare programs, including if drug prices increase at a higher rate than inflation; controls on healthcare providers; challenges to or limits on the pricing of drugs, including pricing controls or limits or prohibitions on reimbursement for specific products through other means; requirements to try less expensive products or generics before a more expensive branded product; and public funding for cost effectiveness research, which may be used by government and private third-party payors to make coverage and payment decisions. Political, economic and regulatory

developments may further complicate developments in healthcare systems and pharmaceutical drug pricing. These developments could, for example, impact our potential licensing agreements as commercial and collaborative partners may also consider the impact of these pressures on their licensing strategies.

Any new laws or regulations that have the effect of imposing additional costs or regulatory burden on pharmaceutical manufacturers, or otherwise negatively affect the industry, could adversely affect our ability to successfully commercialize our product candidates. The implementation of any price controls, caps on prescription drugs or price transparency requirements could adversely affect our business, operating results and financial condition.

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 healthcare laws and regulations, including conflict of interest laws. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations.

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 costs and management attention. 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, we may be subject to unfavorable pricing regulations and/or third-party coverage and reimbursement policies, and we may not be able to offer such product candidates at competitive prices, which could seriously harm our business.

We intend to seek approval to market our product candidates in the United States and in selected foreign jurisdictions, and we will be subject to rules and regulations in those jurisdictions where we obtain approval. 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. In some jurisdictions, government authorities and other third-party payors decide which medications they will pay for and establish reimbursement levels, and 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 could 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, the U.S. Physician Payments Sunshine 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. If the UK or EU Member States were to significantly alter their regulations affecting the pricing of prescription pharmaceuticals, we could face significant new costs.

Risks Related to Our Intellectual Property

Our ability to obtain, maintain, 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 and License Agreements with Paragon 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 programs and our product candidates and their uses, as well as our ability to operate without infringing on or violating the proprietary rights of others. We and Paragon have filed, and may continue to file, provisional and non-provisional patent applications directed to antibodies that target IL-23, including applications covering composition of matter, pharmaceutical formulations, and methods of use, including ORKA-001. In addition, we and Paragon have filed, and may continue to file, provisional and non-provisional patent applications directed to antibodies that target IL-17, including applications covering composition of matter, pharmaceutical formulations, and methods of use, 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 is 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, or invalidated by third parties, or will 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 personnel 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 agreements, such as confidentiality agreements, with our vendors, 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. Enforcing a claim that a party illegally obtained and is using our trade secrets is challenging and the outcome is unpredictable. In addition, courts outside of the U.S. may be less willing to protect trade secrets. 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. 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. We may be unable to acquire or in-license any compositions, methods of use, processes or other 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 or maintain the existing intellectual property rights we do obtain, we may have to abandon the 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 patent 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, 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 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. Moreover, 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.

Failure to obtain licenses at a reasonable cost or on reasonable terms may require us 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. This could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

Disputes may arise between us and our future licensors regarding intellectual property subject to a license agreement, including without limitation: the scope of rights granted under the license agreement and other interpretation-related issues; whether and the extent to which our technology and processes may 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 biopharmaceutical 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. Third-party patent rights, 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 or delay the development of any affected product candidate, and/or seek a license from the patent holder. Any intellectual property claims 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 litigation. Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they may have substantially greater resources. In addition, any litigation could have a material adverse effect on our business and operations, including 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, and any such claims could provoke these parties to assert counterclaims against us. 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 ("marks") 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 of, affect the 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.

Changes to patent laws in the U.S. 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 U.S. and foreign jurisdictions 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. Additionally, there have been proposals for additional changes to the patent laws of the U.S. 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, the USPTO, and the relevant law-making bodies in other countries, 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. In addition, geopolitical instability could increase the uncertainties and costs surrounding the prosecution or maintenance of patent applications and the maintenance, enforcement, or defense of issued patents.

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 U.S. Supreme Court in Amgen, Inc. v. Sanofi (Amgen) 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.

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 U.S. 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 U.S. 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 U.S. may be maintained in secrecy until the patents are issued, and because patent applications in the U.S. 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 impact the validity of the patents issuing thereon. 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.

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 U.S., if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is time 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.

In addition, 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.

Risks Related to Our Reliance on Third Parties

We currently rely on licensing arrangements for a substantial portion of our product portfolio, including with Paragon for ORKA-001 and ORKA-002. 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.

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, their obligations under their agreement with us, disagrees with our interpretation of the terms of such agreement or terminates their agreement with us, our development timeline could be adversely affected. We currently rely on our licensing agreements with Paragon for a substantial portion of our product portfolio, including for ORKA-001 and ORKA-002. 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, partnerships, 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 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 institutions, CROs, contract testing labs, CMOs and strategic partners, to supply, conduct, and support our preclinical studies and clinical trials pursuant to 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. Moreover, our business may be implicated if any of these third parties violate federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Although we have remedies available to us under our agreements, any third parties conducting our preclinical studies or clinical trials will not be our employees and we cannot control whether they devote sufficient time and resources to our programs. These third parties 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.

We rely 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 do not control the manufacturing process of, and are 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, proposed or actual legislative changes or requirements, 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.

Foreign CMOs may be subject to U.S. legislation, including the BIOSECURE Act, trade restrictions, and other foreign regulatory requirements, which could increase costs, reduce the availability of materials, delay procurement or supply, or otherwise adversely affect our operations. We currently rely on foreign CROs and CMOs, including WuXi Biologics (Hong Kong) Limited and its affiliates ("WuXi Biologics"), and we expect to continue to rely on foreign CROs and CMOs in the future.

The BIOSECURE Act was enacted into U.S. law in December 2025 and restricts U.S. federal agencies, as well as recipients of certain federal funding, from procuring, using, or contracting for biotechnology equipment or services from entities designated as "biotechnology companies of concern". The law contemplates a designation process to identify such biotechnology companies of concern, and the timing, scope, and implementation of the Act, including the criteria for designation and the application of any transition or grandfathering provisions, remain subject to ongoing rulemaking and agency interpretation.

WuXi Biologics has been identified in prior legislative proposals and public discourse as a potential biotechnology company of concern; however, it has not been automatically designated as such under the enacted statute. If WuXi Biologics or other third-party providers we rely on were to be designated as biotechnology companies of concern in the future, or if the BIOSECURE Act were otherwise interpreted or implemented in a manner that restricts our

ability to use their services, we could be required to transition to alternative providers, experience supply disruptions or increased costs, or be limited in our ability to access U.S. federal government contracts, grants, or other funding opportunities, which could materially adversely affect our business, financial condition, or results of operations.

Furthermore, 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 geopolitical instability affecting our collaborators in China could introduce delays into the development program. For example, in April 2025, the United States government imposed significant tariffs on imports from China and other countries and may impose more restrictions on goods, including biologically derived substances, manufactured in or imported from China or other countries, or impose other restrictions on companies' ability to work with Chinese or other foreign counterparties. To the extent these or future tariffs are applicable to the material we import from China and other countries or if we are not able to secure supply of our product candidates as a result of applicable legislation, our business and financial condition could be adversely affected.

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 grow the size of our organization, including an increase 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.

Our ability to pursue our growth strategy will be limited if we are unable to continue to attract and retain high quality personnel. 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 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, as well as from universities and research institutions.

In addition, we rely on consultants and 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.

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 biopharmaceutical industry, in addition to our employees, we engage the services of consultants and independent contractors to assist us in the development of our programs. Many of these consultants, independent contractors, and our employees, may have been 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. Although we try to ensure that our employees, consultants, and independent contractors 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 individual 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 or our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees, consultants or independent contractors, each of which would have an adverse effect on our business, results of operations, and financial condition.

Our future growth may depend, in part, on our ability to operate in foreign markets, where we 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. If we fail to comply with the regulatory requirements in foreign 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 commercialize 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 employees, independent contractors, consultants, advisors, 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, advisors, 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 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). 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.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. Further, cybersecurity breaches or other cybersecurity incidents may allow hackers access to our preclinical compounds, strategies, discoveries, trade secrets, and/or other confidential information. Additionally, sensitive data could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel's, vendors' or partners' use of generative AI technologies. Our ability to monitor third parties' information security practices is limited, and these third parties may not have adequate security measures in place. 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. Moreover, while we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient or we may be unable to recover such award. Security incidents and attendant consequences may negatively impact our ability to grow and operate our business. The risk of a cybersecurity incident or other information technology disruption, particularly through cyber-attacks, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased.

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 (including clinical trial data) or applications, or for it to be believed or reported that any of these occurred, we could incur liability, including under laws and regulations governing the protection of protected health information and other personal data, 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.

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, contractors, 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 or from cyber-attacks by malicious third parties, or ransomware attacks, which, in each case, may compromise our system infrastructure or lead to the loss, destruction, alteration or dissemination of, or damage to, our data.

Our hybrid-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.

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, data transfer, 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 U.S. 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 IRA, 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. 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 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. 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 that may not prove to be accurate. 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 product liability claims and our 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. The use of a product candidate in clinical trials and the sale of any approved products in the future may expose us to liability claims. An individual or group of individuals may bring a liability claim against us if one of our product candidates causes, or merely appears to have caused, an injury, either at the clinical or commercial stage. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially and adversely affect our business. While we carry product liability insurance for our 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. On occasion, large judgments have been awarded in class action or individual lawsuits. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could decrease our cash 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 and may experience in the future extreme volatility and disruptions, including, among other things, diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, new or increased tariffs, and other barriers to trade, especially in light of recent executive orders made by the Trump administration, trade and other international disputes, increases in inflation rates, fluctuation in interest rates, slower growth or recession, tighter credit, volatility in financial markets, high unemployment, labor availability constraints, public health crises, significant natural disasters, changes to fiscal and monetary policy, or government budget dynamics (particularly in the pharmaceutical and biotechnology areas), political and military conflict, and uncertainty about economic stability. Recently, the U.S. has announced tariffs on imports from most countries, including significant tariffs on imports from China. Historically, tariffs have led to increased trade and political tensions. In response to tariffs, other countries have implemented retaliatory tariffs on U.S. goods. Political tensions as a result of trade policies could reduce trade

volume, investment, technological exchange, and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets. There is substantial uncertainty about the duration of existing tariffs and whether additional tariffs may be imposed, modified or suspended. 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 economic or political uncertainty, 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.

Geopolitical events and global economic conditions may also affect the ability of the FDA and other regulatory authorities to perform routine functions. If such concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Risks Related to Owning Our Stock

The market price of our common stock has been, and may continue to be, volatile.

The market price of our common stock has been and is likely to be highly volatile and is subject to significant fluctuations. 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. For example, escalating trade tensions, elevated interest rates, and regulatory uncertainty have caused significant market volatility recently, and particularly in the biotechnology and biopharmaceutical industries. 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 securities litigation or increased stockholder 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. Class action securities litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation.

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;
- Actions taken by regulatory agencies with respect to our product candidates, clinical studies, manufacturing process, or sales and marketing terms;

- Failure to meet or exceed the financial and development projections of the investment community or 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;
- General market, macroeconomic, geopolitical conditions, or market conditions in the pharmaceutical and biotechnology sectors;
- Announcements of significant acquisitions, strategic collaborations, joint ventures, or capital commitments by us or our competitors;
- 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;
- Changes in the market valuations of similar companies;
- Sales of securities by us or our securityholders in the future, or the anticipation of such events;
- Failure 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 products, clinical progress or lack thereof, significant contracts, commercial relationships, or capital commitments;
- The introduction of technological innovations or new therapies that compete with our products; and
- Period-to-period fluctuations in our financial results.

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 more than 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, or the anticipation of such events, 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, the trading price of our common stock could decline. In October 2025 we filed a registration statement on Form S-3 covering the resale of 39,425,806 shares of our common stock (including shares of common stock issuable upon the conversion of outstanding Series B Preferred Stock, or issuable upon the exercise of outstanding pre-funded warrants to purchase shares of common stock). The sale of these shares in the public market or the perception that holders of a large number of the securities intend to sell their securities could significantly reduce the price of our common stock. We cannot predict if and when the selling stockholders listed in the registration statement may sell such shares in the public markets. 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. Furthermore, in the future, we may issue additional shares of common stock or other equity or debt securities convertible into shares of common stock.

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 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

We collect, use, store, and transmit confidential, sensitive, proprietary, personal, and health-related information in the ordinary course of our business. As such, we leverage third-party information technology service providers who have implemented and maintain various information security processes designed to identify, assess, and manage material risks from cybersecurity threats to our information technology systems, including critical computer networks, third party hosted services, communications systems, hardware and software, and our data residing on these systems. Our Senior Vice President, Finance is responsible for overseeing these third-party service providers and processes.

Cybersecurity risks are identified by monitoring and evaluating our threat environment, and then assessed by various methods, for example, by manual and automated tools designed to identify and combat cybersecurity threats, analyzing reports of threats, conducting scans and assessments of the threat environment and to identify vulnerabilities, the use of detection and response services and conducting reviews of third-party service providers, among other things. Depending on the threat environment, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our information systems and data, including, for example, physical security and access controls, asset management, systems monitoring, incident detection and response, risk assessment, the implementation of security standards and certifications, encryption of data, network security controls, and a recovery/business continuity plan, among other mitigation tactics. Our recovery/business continuity plan is designed to mitigate and remediate identified cybersecurity incidents and escalate certain incidents as appropriate to management and the Audit Committee. We plan to conduct due diligence on and audits of key technology vendors, contract research organizations, and other third-party contractors and suppliers. Additionally, we conduct periodic employee training that covers cyber and information security, among other topics.

Our assessment and management of material risks from cybersecurity threats are integrated into the Company's overall risk management process. Our Senior Vice President, Finance, who reports directly to the Chief Executive Officer, together with our senior management, is responsible for assessing and managing cybersecurity risks with support from our third-party information technology service providers that employ information technology consultants with over 20 years of experience managing cybersecurity programs. Our cybersecurity program aligns to the National Institute of Standards and Technology (NIST) Cybersecurity Framework (CSF) and is consistently updated as NIST recommendations change year over year. Our Senior Vice President, Finance, together with our senior management and other employees, works closely with our information technology service providers to evaluate material cybersecurity threats against our overall business objectives as part of our cybersecurity incident response. The Board of Directors, as a whole and at the committee level, has oversight for the most significant risks facing us and for our processes to identify, prioritize, assess, manage and mitigate those risks. The Audit Committee has been designated by our Board to oversee cybersecurity risks. The Audit Committee receives regular updates on cybersecurity and information technology matters and related risk exposures from our Senior Vice President, Finance. The Board also receives updates from management and the Audit Committee on cybersecurity risks on a regular basis.

In the last fiscal year, we have not identified any risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected us, but we face certain ongoing cybersecurity risks or threats that, if realized, are reasonably likely to materially affect us. For a description of the risks from cybersecurity threats that may materially affect the Company and how they may do so, see our "Risk Factors" under Part 1 Item 1A. Risk Factors, in this Annual Report on Form 10-K.

Item 2. Properties.

Our corporate headquarters are in Menlo Park, California and we have an additional office in Waltham, Massachusetts. Our lease for our Menlo Park headquarters expires on September 30, 2027 and our lease for our Waltham office expires on September 30, 2029. We believe our current facilities are sufficient for our needs for the foreseeable future.

Item 3. 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 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock is traded on the Nasdaq Global Market under the symbol "ORKA".

Holders of Record

As of February 28, 2026, there were approximately 36 stockholders of record of our common stock based on information provided by our transfer agent. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. The number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividends

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. We do not intend to pay cash dividends on our common stock for the foreseeable future.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Performance Graph

As a "smaller reporting company," as defined by Rule 12b-2 of the Exchange Act, and pursuant to Instruction 6 to Item 201(e) of Regulation S-K, we are not required to provide the stock performance graph.

Item 6. [Reserved]

Item 7. 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 consolidated financial statements and the related notes included elsewhere in this Annual Report on Form 10-K for the year ended December 31, 2025 (this "Annual 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 Annual Report entitled "Risk Factors" and elsewhere in this Annual 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 Annual Report. As used in this Annual 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 subsidiary, Oruka Therapeutics Operating Company LLC, taken as a whole.

Overview

We are a clinical-stage biopharmaceutical 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 most 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 reducing 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 ("TRMs").

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, hidradenitis suppurativa ("HS"), 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 our company, business and scientific planning, conducting discovery and research activities, establishing and protecting our intellectual property portfolio, establishing arrangements with third parties for the manufacture of our programs and component materials, developing and progressing our pipeline, and providing general and administrative support for these operations. We do not have any products 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, a convertible note, pre-funded warrants, and the proceeds from the reverse recapitalization and merger, our Pre-Closing Financing and subsequent PIPE Financings (as defined and further described 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. As of December 31, 2025, we had an accumulated deficit of $189.2 million. For the year ended December 31, 2025, we had net losses of $105.4 million, and we used net cash of $88.2 million for our operating activities.

We had cash, cash equivalents, and marketable securities of $479.6 million as of December 31, 2025. We expect that our existing cash, cash equivalents, and marketable securities will be sufficient to fund our operating plans for at least twelve months from the date of the filing of this Annual 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.

Our Portfolio and Development Plans

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 clinical 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 fragment crystallizable ("Fc") domain to modify the pH-dependent binding to the neonatal Fc receptor ("FcRn"). As a result, it has a pharmacokinetic profile designed to support a subcutaneous ("SQ") injection as infrequently as once or twice per 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 initiated a Phase 1 trial of ORKA-001 in the fourth quarter of 2024 and in September 2025, we announced interim results at the European Academy of Dermatology and Venereology (EADV) Congress. The data showed that ORKA-001 has a human half-life of approximately 100 days. Single doses of ORKA-001 demonstrated complete and sustained inhibition of STAT3 signaling, a downstream marker of IL-23 activity, in an ex vivo assay through 24 weeks. In addition, ORKA-001 was well tolerated at all dose levels, with a favorable safety profile consistent with the anti-IL-23 class.

In the third quarter of 2025, we commenced dosing in a Phase 2a clinical trial of ORKA-001 in patients with moderate-to-severe PsO (also known as "EVERLAST-A"). We expect to share Week 16 data for all patients in the second quarter of 2026. In addition, we plan to share longer-term data, including Week 28 for all patients and 52-week follow-up for a portion of the cohort in the second half of 2026. EVERLAST-A enrolled 84 patients randomized 3:1 to receive 600 mg of ORKA-001 at Weeks 0 and 4 or matching placebo. The primary endpoint is PASI 100, a 100% reduction from baseline in the Psoriasis Area and Severity Index ("PASI"), at Week 16. At Week 28, patients who have achieved PASI 100 will be randomized 2:1 to an arm where either (1) they do not receive another dose until disease recurrence (to evaluate the possibility of both yearly dosing and extended off-treatment remissions) or (2) they receive 300 mg ORKA-001 every six months.

Additionally, the first patients were dosed in EVERLAST-B in December 2025. EVERLAST-B is designed to enroll approximately 160 patients into a dose-ranging Phase 2b trial of ORKA-001 in patients with moderate-to-severe PsO and will evaluate three dose levels of ORKA-001: 37.5 mg at Week 0, 300 mg at Weeks 0 and 4, and 600 mg at Weeks 0 and 4, versus placebo. The primary endpoint is PASI 100 at Week 16. At Week 28, patients who have achieved PASI 100 will be re-randomized 1:1 to either a 600 mg dose once-yearly or placebo. Patients who have not achieved PASI 100 at Week 28 will receive a 300 mg dose every six months. Building on EVERLAST-A, this design will further test the potential for ORKA-001 to achieve yearly dosing, higher efficacy and extended off-treatment remissions. Data from EVERLAST-B is anticipated in 2027.

Based on recent precedent in PsO, we anticipate that the overall development program, from first-in-human studies through biologics license application ("BLA") submission, could take as little as six to seven years, based on averages observed for recently approved medicines. However, we have no control over the duration of the United States Food and Drug Administration ("FDA") review process, and the actual timeline may vary.

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 HS and axial spondyloarthritis ("axSpA"). 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.

In January 2026, we announced interim findings from the Phase 1 trial of ORKA-002 in healthy volunteers. The results showed that ORKA-002 has a half-life of approximately 75-80 days, which supports the potential for twice-yearly maintenance dosing in PsO and quarterly maintenance dosing in HS. Single doses of ORKA-002 demonstrated potent and sustained inhibition of IL-17 signaling in an ex vivo assay through 24 weeks. ORKA-002 was well tolerated at all dose levels, with a favorable safety profile consistent with the anti-IL-17 class. The trial remains blinded, and as of January 6, 2026, which was the data cutoff date, all subjects remained on trial.

Based on these Phase 1 results, we initiated ORCA-SURGE, a Phase 2 trial of ORKA-002 in patients with moderate-to-severe PsO, in February 2026. ORCA-SURGE is designed to enroll approximately 160 patients randomized 1:1:1:1 to receive 40 mg, 160 mg or 320 mg of ORKA-002 at Weeks 0 and 4, or matching placebo. The primary endpoint is PASI 100 at Week 16. Maintenance dosing will evaluate the potential for twice-yearly dosing with ORKA-002. Data from ORCA-SURGE is anticipated in 2027. Moreover, we also expect to initiate a Phase 2 trial of ORKA-002 in patients with HS in the second half of 2026.

Additional Pipeline Program

We have a third 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.

Acquisition of Pre-Merger Oruka

On August 29, 2024 (the "Closing"), we completed the acquisition (the "Merger") of the private company, Oruka Therapeutics, Inc. ("Pre-Merger Oruka"), a pre-clinical stage biotechnology company that was incorporated on February 6, 2024 for the purposes of holding rights to certain intellectual property being developed by Paragon Therapeutics, Inc. ("Paragon"). On August 29, 2024, we changed our name from "ARCA biopharma, Inc." to "Oruka Therapeutics, Inc." and our Nasdaq ticker symbol from "ABIO" to "ORKA". Following consummation of the Merger, we effected a 1-for-12 reverse stock split (the "Reverse Stock Split") of our common stock, par value $0.001 per share, of the Company ("Company Common Stock"). The Company Common Stock commenced trading on a post-Reverse Stock Split, post-Merger basis at the opening of trading on September 3, 2024. All references to common stock, options to purchase common stock, outstanding common stock warrants, common stock share data, per share data, Company Common Stock, and related information contained in the 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.

Pre-Closing Financing and Closing

Immediately prior to the execution and delivery of the Merger Agreement, certain new and existing investors of Pre-Merger Oruka entered into a subscription agreement with Pre-Merger Oruka (that was subsequently amended and restated in July 2024, 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 9 to the consolidated financial statement) 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 were recorded as a reduction to additional paid-in capital in the consolidated financial statements.

In connection with 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 to purchase Company Common Stock in accordance with the Exchange Ratio (as defined below and determined by the terms of the Merger Agreement). Moreover, as part of the Closing of the Merger, (i) then-issued and outstanding shares 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") 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 after the Reverse Stock Split, (iii) each outstanding option to purchase Pre-Merger Oruka Common Stock was converted into an option to purchase shares of Company Common Stock, and (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.

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 owned a substantial majority of the voting rights in the combined company; (ii) Pre-Merger Oruka's largest stockholders retained 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: (a) the Merger was treated as the equivalent of Pre-Merger Oruka issuing stock to acquire the net assets of ARCA, and (b) the reported historical operating results of the combined company prior to the Merger are those of Pre-Merger Oruka. As part of the reverse recapitalization, the Company acquired a cash balance of $4.94 million from ARCA.

Additional information regarding the Merger is included in Note 3 to the consolidated financial statements included in Part II — Item 8 of this Annual Report.

PIPE Financings

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

Pursuant to the 2024 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 our 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 $11.9 million).

On September 17, 2025, we entered into a Securities Purchase Agreement (the "2025 Securities Purchase Agreement") for a private placement (the "2025 PIPE Financing") with certain institutional and accredited investors. The closing of the 2025 PIPE Financing occurred on September 19, 2025.

Pursuant to the 2025 Securities Purchase Agreement, the investors purchased an aggregate of 10,933,405 shares of Company Common Stock at a purchase price of $15.00 per share, and pre-funded warrants to purchase an aggregate of 1,066,666 shares of Company Common Stock at a purchase price of $14.999 per pre-funded warrant, for aggregate net proceeds of approximately $169.6 million (net of issuance costs of $10.4 million).

Paragon Therapeutics — Option and License Agreements

Option Agreements — Paragon Therapeutics

In March 2024, we entered into two antibody discovery and option agreements (the "Option Agreements") with Paragon Therapeutics, Inc. ("Paragon") and Paruka Holdings LLC ("Paruka"). Under the terms of each agreement, Paragon identifies, evaluates, and develops antibodies directed against certain mutually agreed therapeutic targets of interest to us. From time to time, we can choose to add additional targets to the collaboration upon agreement with Paragon and Paruka. Under the Option Agreements, we have the exclusive option to, on a research program-by-research program basis, be granted an exclusive, worldwide license to all of Paragon's rights, titles, 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) (each, an "Option"). We have initiated certain research programs with Paragon that generally focus on discovering, generating, identifying and/or

characterizing antibodies directed to a particular target (each, a "Research Program"), including for IL-23 and IL-17A/F for ORKA-001 and ORKA-002, respectively. The exclusive option with respect to each Research Program is exercisable at our sole discretion at such time as specified in the Option Agreements (the "Option Period"). There is no payment due upon exercise of an Option pursuant to the Option Agreements.

In December 2025, we entered into an additional option agreement for an antibody with Paragon and Paruka to enter into a license agreement, which we exercised in December 2025. For the year ended December 31, 2025 we incurred $1.5 million related to this additional option agreement which was recognized as research and development expense. Per the terms of this option agreement, once we enter into the corresponding license agreement, we will be required to make non-refundable milestone payments to Paragon of up to $12.0 million under the agreement upon the achievement of certain clinical development milestones, up to $10.0 million under the agreement upon the achievement of certain regulatory milestones, as well as a low single-digit percentage royalty for antibody products beginning on the first commercial sale. As of December 31, 2025, we have not entered into a license agreement with Paragon and Paruka related to this additional option agreement.

As part of the Option Agreements and the additional option agreement mentioned above, on December 31, 2024, we settled our 2024 obligations under the Paruka Warrant Obligation by issuing Paruka a warrant to purchase 596,930 shares of Company Common Stock at an exercise price of $19.39 per share, and on December 12, 2025, we settled our 2025 obligations under the Paruka Warrant Obligation by issuing Paruka a warrant to purchase 375,000 shares of Company Common Stock at an exercise price of $30.18 per share.

License Agreements — Paragon Therapeutics

In September 2024, we exercised our exclusive option to acquire certain rights to ORKA-001, and in December 2024, we entered into a corresponding license agreement with Paragon (the "ORKA-001 License Agreement"), pursuant to which Paragon granted us a royalty-bearing, world-wide, exclusive license to develop, manufacture, commercialize, or otherwise exploit certain antibodies and products targeting IL-23 in all fields other than the field of inflammatory bowel disease ("ORKA-001 Field"). In December 2024, we exercised our exclusive option to acquire certain rights to ORKA-002, and in February 2025, we entered into the corresponding license agreement with Paragon (the "ORKA-002 License Agreement" and together with the ORKA-001 License Agreement, the "License Agreements"), pursuant to which Paragon granted us a royalty-bearing, world-wide, exclusive license to develop, manufacture, commercialize, or otherwise exploit certain antibodies and products targeting IL-17A/F in all fields ("ORKA-002 Field" and together with the ORKA-001 Field, the "Fields"). Pursuant to each of the two License Agreements, Paragon has agreed not to conduct any new campaigns that generate anti-IL-23 monospecific antibodies or anti-IL-17A/F monospecific antibodies in the respective agreed-upon fields.

The License Agreements provide us with exclusive licenses in the Fields to Paragon's patent applications covering the related antibodies, their method of use and their method of manufacture and Paragon has agreed not to conduct any new campaigns that generate anti-IL-23 monospecific antibodies or anti-IL-17A/F monospecific antibodies for the ORKA-001 Field or the ORKA-002 Field, respectively, for at least five years. Each of the License Agreements may be terminated on 60 days' notice to Paragon, on material breach without cure, and on a party's insolvency or bankruptcy to the extent permitted by law.

Pursuant to the terms of each of the License Agreements, we are obligated to pay Paragon non-refundable milestone payments of up to $12.0 million under each respective agreement upon the achievement of certain clinical development milestones and up to $10.0 million under each respective agreement upon the achievement of certain regulatory milestones. In addition, we are obligated to pay Paragon a low single-digit percentage royalty for antibody products for each of ORKA-001 and ORKA-002. For each of the License Agreements, the royalty term ends on the later of (i) the last-to-expire licensed patent or our patent directed to the manufacture, use or sale of a licensed antibody in the country at issue or (ii) 12 years from the date of first sale of a Company product. There is also a royalty step-down if there is no Paragon patent in effect during the royalty term for each program. Each of the License Agreements may be terminated on 60 days' notice to Paragon, on material breach without cure, and on a party's insolvency or bankruptcy to the extent permitted by law. As of December 31, 2025, we have incurred and expensed milestone payments of $7.0 million and $4.0 million in connection with the ORKA-001 License Agreement and the ORKA-002 License Agreement, respectively.

Pursuant to the Option Agreements and License 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 certain initiation fees, development costs and milestone payments to Paragon.

For the ORKA-001 program, we recognized research and development expenses related to the following milestones during the period from February 6, 2024 (inception) to December 31, 2024: a one-time, nonrefundable research initiation fee of $0.8 million; $1.5 million related to exercising our Option and achievement of development candidate; and $2.5 million related to completing the first dosing of a human subject in a Phase 1 trial. We were responsible for 50% of the development costs incurred through the completion of the IL-23 selection process, which was completed in June 2024. An amount of $13.5 million was incurred during the period from February 6, 2024 (inception) to December 31, 2024 for research and development expenses for the ORKA-001 program.

For the ORKA-002 program, we recognized research and development expenses related to the following milestones during the period from February 6, 2024 (inception) to December 31, 2024: a one-time, nonrefundable research initiation fee of $0.8 million and $1.5 million related to exercising our Option and achievement of development candidate. We were responsible for the development costs incurred through the completion of the IL-23 selection process, which was completed in December 2024. An amount of $11.1 million was incurred during the period from February 6, 2024 (inception) to December 31, 2024 for research and development expenses for the ORKA-002 program.

Pursuant to the Option Agreements and License Agreements, for year ended December 31, 2025, our share of research and development expenses for the ORKA-001 program was nil. We recognized a milestone payment of $3.0 million related to completing the first dosing of a human patient in a Phase 2 trial for the ORKA-001 program during the year ended December 31, 2025. These costs were recorded as research and development expenses. As of December 31, 2025 and 2024, nil and $2.8 million, respectively, related to ORKA-001 were included in related party accounts payable and other current liabilities.

Pursuant to the Option Agreements and License Agreements, for the year ended December 31, 2025, our share of research and development expense for the ORKA-002 program was $0.1 million. We recognized a milestone payment of $2.5 million related to completing the first dosing of a human subject in a Phase 1 trial for the ORKA-002 program during the year ended December 31, 2025. These costs were recorded as research and development expenses. As of December 31, 2025 and 2024, nil and $2.7 million, respectively, related to ORKA-002 were included in related party accounts payable and other current liabilities.

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 consolidated statements of operations.

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 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.

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 that conduct research and development activities on our behalf;
- costs incurred, and milestone payments under license and option agreements;
- 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;
- expenses incurred under agreements with contract research organizations ("CROs"), contract manufacturing organizations ("CMOs"), and with clinical trial sites that conduct research and development activities on our behalf;
- the cost of development and validating our manufacturing process for use in our preclinical studies and current and future clinical trials;
- personnel-related expenses, including salaries, bonuses, employee benefits, travel, and 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. Non-refundable advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. 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. 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. See "Contractual Obligations and Commitments" below for further details.

We expect our research and development expenses will increase substantially for the foreseeable future as we continue to invest in research and development activities related to the continued development of our programs, developing any future programs, including investments in manufacturing, as we advance any program we may identify and continue to conduct clinical trials. The success of programs we may identify and develop will depend on many factors, including the following:

- timely and successful completion of preclinical studies and clinical trials;
- effective investigational new drug ("IND") or comparable foreign applications that allow commencement of our planned clinical trials or future clinical trials for any programs we may develop;
- successful enrollment and completion of clinical trials;

- positive results from our clinical trials that support a finding of safety and effectiveness, acceptable pharmacokinetics profile, and an acceptable risk-benefit profile in the intended populations;
- receipt of marketing approvals from applicable regulatory authorities;
- establishment of arrangements through our own facilities or with third-party manufacturers for clinical supply and, where applicable, commercial manufacturing capabilities; and
- maintenance of a continued acceptable safety, tolerability, and efficacy profile of any programs we may develop following approval.

Any changes in the outcome of any of these variables with respect to the development of programs that we may identify could mean a significant change in the costs and possible delays in timing associated with the development of such programs. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development of a program, or if we experience significant delays in our clinical trials due to patient enrollment or other reasons, we would be required to expend significant additional financial resources and time on the completion of clinical development. We may never obtain regulatory approval for any of our programs.

General and Administrative

General and administrative expenses consist primarily of personnel-related expenses, including salaries, bonuses, employee benefits, travel, 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; 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

Total other income (expense), net consists of interest earned on our cash, cash equivalents, and marketable securities; interest expense on the convertible note from a related party (see discussion herein); 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"), a related party, in March 2024. At the effective time of the Merger, the Convertible Note, along with the accrued interest, was automatically converted into Company Common Stock.

Income Taxes

No provision for income taxes was recorded for the year ended December 31, 2025 and for the period from February 6, 2024 (inception) to December 31, 2024. Deferred tax assets generated from our net operating losses have been fully offset by the valuation allowance as we believe it is not more likely than not that the benefit will be realized due to our cumulative losses generated to date.

Results of Operations

Comparison of the Year Ended December 31, 2025 and the period from February 6, 2024 (inception) to December 31, 2024

The following table summarizes our results of operations for the periods presented (in thousands):

	Year Ended December 31, 2025	Period from February 6, 2024 (inception) to December 31, 2024	Change $	Change %
Operating expenses				
Research and development[(1)]	$ 100,640	$ 75,060	$ 25,580	34%
General and administrative[(2)]	21,411	13,063	8,348	64%
Total operating expenses	122,051	88,123	33,928	39%
Loss from operations	(122,051)	(88,123)	(33,928)	39%
Other income (expense)				
Interest income	16,630	5,863	10,767	184%
Interest expense[(3)]	—	(1,468)	1,468	(100)%
Other income (expense), net	(12)	4	(16)	*
Total other income, net	16,618	4,399	12,219	*
Net loss	$ (105,433)	$ (83,724)	$ (21,709)	26%

* Percentage not meaningful

(1) Includes related party amounts of $17,129 and $42,640 for the year ended December 31, 2025 and the period from February 6, 2024 (inception) to December 31, 2024, respectively.

(2) Includes related party amounts of $139 and $1,364 for the year ended December 31, 2025 and the period from February 6, 2024 (inception) to December 31, 2024, respectively.

(3) Includes related party amounts of nil and $1,468 for the year ended December 31, 2025 and the period from February 6, 2024 (inception) to December 31, 2024, respectively.

Research and Development Expenses

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

	Year Ended December 31, 2025	Period from February 6, 2024 (inception) to December 31, 2024	Change $	Change %
External research and development expenses	$ 64,378	$ 57,680	$ 6,698	12%
Other research and development expenses:				
Personnel-related (excluding stock-based compensation)	14,957	3,959	10,998	*
Stock-based compensation	17,019	11,992	5,027	42%
Other	4,286	1,429	2,857	*
Total research and development expenses	$ 100,640	$ 75,060	$ 25,580	34%

* Percentage not meaningful

Research and development expenses increased by $25.6 million from $75.1 million for the period from February 6, 2024 (inception) to December 31, 2024 to $100.6 million for the year ended December 31, 2025.

External research and development expenses, including CROs, CMOs, and other third-party preclinical studies and clinical trials expenses, increased by $6.7 million, from $57.7 million for the period from February 6, 2024 (inception) to December 31, 2024 to $64.4 million for the year ended December 31, 2025. The increase is primarily related to increased CMO product development and manufacturing expenses, an increase in our CRO expenses related to our ongoing clinical trials and toxicology studies, partially offset by a reduction of research expenses incurred by Paragon.

Personnel-related expenses increased by $11.0 million, from $4.0 million for the period from February 6, 2024 (inception) to December 31, 2024 to $15.0 million for the year ended December 31, 2025, as we continue hiring employees in our research and development organization. Stock-based compensation expense increased by $5.0 million, from $12.0 million for the period from February 6, 2024 (inception) to December 31, 2024 to $17.0 million for the year ended December 31, 2025. Stock-based compensation expense increased due to the increase in employee awards.

Other research and development expenses increased by $2.9 million, from $1.4 million for the period from February 6, 2024 (inception) to December 31, 2024 to $4.3 million for the year ended December 31, 2025, primarily due to higher share of allocated overhead expenses for facilities and information technology due to an increase in our research and development employee count.

General and Administrative Expenses

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

	Year Ended December 31, 2025	Period from February 6, 2024 (inception) to December 31, 2024	Change	
			$	%
Personnel-related (including stock-based compensation)	$ 15,032	$ 7,981	$ 7,051	88%
Professional and consulting services	5,534	4,606	928	20%
Other	845	476	369	78%
Total general and administrative expenses	$ 21,411	$ 13,063	$ 8,348	64%

General and administrative expenses increased by $8.3 million from $13.1 million for the period from February 6, 2024 (inception) to December 31, 2024 to $21.4 million for the year ended December 31, 2025.

Personnel-related expenses increased by $7.0 million, from $8.0 million for the period from February 6, 2024 (inception) to December 31, 2024 to $15.0 million for the year ended December 31, 2025, as a result of continued hiring of executives and administrative employees. Stock-based compensation expenses were $2.9 million and $7.2 million for the period from February 6, 2024 (inception) to December 31, 2024 and for the year ended December 31, 2025, respectively.

Professional and consulting services expenses increased by $0.9 million, from $4.6 million for the period from February 6, 2024 (inception) to December 31, 2024 to $5.5 million for the year ended December 31, 2025, due to higher spending on legal and other professional services.

Other general and administrative expenses increased by $0.4 million, from $0.5 million for the period from February 6, 2024 (inception) to December 31, 2024 to $0.9 million for the year ended December 31, 2025, primarily due to increase in facilities and information technology services expenses, partially offset by a higher allocation of overhead expenses to research and development expenses as a result of an increase in our research and development employee count.

Total Other Income, Net

Interest income from cash equivalents and marketable securities increased by $10.8 million, from $5.9 million for the period from February 6, 2024 (inception) to December 31, 2024 to $16.6 million for the year ended December 31, 2025. The increase was primarily due to higher invested balances.

No interest expense was recorded during the year ended December 31, 2025. Interest expense was $1.5 million for the period from February 6, 2024 (inception) to December 31, 2024 relating to the Convertible Note from Fairmount.

Liquidity and Capital Resources

As of December 31, 2025, we had $479.6 million of cash, cash equivalents, and marketable securities.

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 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. Through December 31, 2025, we had funded our operations primarily with proceeds from issuances of convertible preferred stock, common stock, a convertible note, and pre-funded warrants.

In October 2025, we entered into a Sales Agreement with TD Securities (USA) LLC (the "Sales Agreement"), as our sales agent, pursuant to which we may issue and sell, from time to time, shares of our common stock for aggregate gross proceeds of up to $200.0 million under an at-the-market equity offering program. We are not obligated to make any sales of shares under the Sales Agreement. As of December 31, 2025, no sales had been made under our at-the-market equity offering program.

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 biopharmaceutical 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, cash equivalents, and marketable securities will be sufficient to fund our operating plans for at least twelve months from the date of filing of this Annual 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 periods presented (in thousands):

	Year Ended December 31, 2025	Period from February 6, 2024 (inception) to December 31, 2024
Net cash used in operating activities	$ (88,210)	$ (57,837)
Net cash used in investing activities	(96,745)	(330,127)
Net cash provided by financing activities	170,315	449,539
Net (decrease) increase in cash and cash equivalents	$ (14,640)	$ 61,575

Operating Activities

For the year ended December 31, 2025, net cash used in operating activities was $88.2 million, which was primarily attributable to a net loss of $105.4 million and net cash used by changes in our operating assets and liabilities of $2.6 million, partially offset by net non-cash charges of $19.8 million. Net cash used by changes in our operating assets and liabilities was primarily comprised of a decrease of $6.0 million in related party accounts payable and other current liabilities, an increase of $4.0 million in prepaid expenses and other current assets, partly offset by an increase of $7.2 million in accrued expenses and other current liabilities, and an increase of $0.7 million in accounts payable balances. Net non-cash charges primarily comprised of $24.2 million in stock-based compensation expense (includes $10.1 million from the Paruka Warrant Obligation, as defined in Note 11 to the consolidated financial statements), partially offset by $5.0 million in net accretion of premiums

and discounts on marketable securities. The decrease in amounts due to related parties was primarily due to lower research expenses incurred with Paragon. The increase in balances for accrued expenses and other current liabilities, and accounts payable 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.

From February 6, 2024 (inception) to December 31, 2024, net cash used in operating activities was $57.8 million, which was primarily attributable to a net loss of $83.7 million, offset by net non-cash charges of $14.3 million and net changes in operating activities of $11.6 million. Non-cash charges primarily consisted of $14.9 million in stock-based compensation expense (including $10.4 million related to the Paruka Warrant Obligation) and $1.5 million of non-cash interest expense, partially offset by net accretion of premiums and discounts on marketable securities of $2.2 million. Net changes in our operating activities primarily consisted of a $3.5 million increase in accounts payable, a $3.3 million increase in accrued expenses and other current liabilities, a $6.0 million increase in related parties accounts payable and other current liabilities, partially offset by a $1.1 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

For the year ended December 31, 2025, net cash used in investing activities was $96.7 million, which included $521.0 million in purchases of marketable securities and $0.2 million in purchases of property and equipment, partially offset by $424.4 million in proceeds from maturities of marketable securities.

From February 6, 2024 (inception) to December 31, 2024, net cash used in investing activities was $330.1 million, which was primarily attributable to purchases of marketable securities.

Financing Activities

For the year ended December 31, 2025, net cash provided by financing activities was $170.3 million, consisting of $169.6 million of net proceeds from the 2025 PIPE Financing and $0.7 million proceeds from the issuance of common stock upon exercise of stock options and employee warrants and purchases under our Employee Stock Purchase Plan.

From February 6, 2024 (inception) to December 31, 2024, net cash provided by financing activities was $449.5 million, consisting of $228.0 million of net proceeds from the Pre-Closing Financing, $188.7 million of net proceeds from the 2024 PIPE Financing, $25.0 million of net proceeds from the issuance of notes payable to related parties, $4.9 million of cash acquired in connection with the reverse recapitalization and $2.9 million of net proceeds from issuance of the Pre-Merger Oruka Series A Preferred Stock.

Contractual Obligations and Commitments

We enter into contracts in the normal course of business with CROs, CMOs and with other vendors for preclinical research studies, clinical trials, manufacturing, 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 December 31, 2025.

Cell Line License Agreement

In March 2024, we entered into the Cell Line License Agreement (the "Cell Line License Agreement") with WuXi Biologics Ireland Limited ("WuXi Biologics"). Under the Cell Line License Agreement, we received a non-exclusive, worldwide, sublicensable license to certain of WuXi Biologics' know-how, cell line, biological materials (the "WuXi Biologics Licensed Technology") and media and feeds to make, have made, use, sell and import certain therapeutic products produced through the use of the cell line licensed by WuXi Biologics under the Cell Line License Agreement (the "WuXi Biologics Licensed Products"). Specifically, the WuXi Biologics Licensed Technology is used in certain manufacturing activities in support of the ORKA-001 and ORKA-002 programs.

In consideration for the license, we agreed to pay WuXi Biologics a non-refundable license fee of $150,000, which was recognized as a research and development expense during the period from February 6, 2024 (inception) to December 31, 2024. Additionally, to the extent that we manufacture our commercial supplies of bulk drug product with a manufacturer other than WuXi Biologics or its affiliates, we are required to make royalty payments to WuXi Biologics at a rate of less than one percent of net sales of WuXi Biologics Licensed Products manufactured by the third-party manufacturer. Pursuant to an amendment to the Cell Line License Agreement effective in November 2024, a provision was added that permits the royalties owed under the agreement to be bought out on a product-by-product basis for a lump-sum payment.

The Cell Line License Agreement will continue indefinitely unless terminated (i) by us upon six months' prior written notice and our payment of all undisputed amounts due to WuXi Biologics through the effective date of termination, (ii) by WuXi Biologics for a material breach by us that remains uncured for 60 days after written notice, (iii) by WuXi Biologics if we fail to make a payment and such failure continues for 30 days after receiving notice of such failure, or (iv) by either party upon the other party's bankruptcy.

Lease Agreement

Our contractual obligations include minimum lease payments under our operating lease obligation for our headquarters in Menlo Park, California and our office in Waltham, Massachusetts. See Note 15 to the consolidated financial statements for additional information.

Option Agreements and License Agreements — Paragon Therapeutics

Our contractual obligations include milestones and royalties payable to Paragon. See Note 14 to the consolidated financial statements for additional information.

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 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 our 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 the consolidated financial statements, we believe the following accounting policies used in the preparation of our financial statements require the most significant judgments and estimates.

Research and Development Expenses

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including salaries and bonuses, overhead costs, contract services and other related costs. The value of goods and services received from contract research organizations and contract manufacturing organizations in the reporting period are estimated based on the level of services performed, and progress in the period in cases when we have not received an invoice from the supplier. In circumstances where amounts have been paid in excess of costs incurred, we record a prepaid expense. When billing terms under these contracts do not coincide with the timing of when the work is performed, we are required to make estimates of outstanding obligations to those third parties as of period end. Any accrual estimates are based on a number of factors, including our knowledge of the progress towards completion of the specific tasks to be performed, invoicing to date under the contracts, communication from the vendors of any actual costs incurred during the period that have not yet been invoiced and the costs included in the contracts. Significant judgments and estimates may be made in determining the accrued balances at the end of any reporting period. Actual results could differ from the estimates made by us.

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 the 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 consolidated financial statements included in Part II — Item 8 of this Annual Report for more information regarding recently issued accounting pronouncements.

Off-Balance Sheet Arrangements

As of December 31, 2025, we did not have any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Item 7A. 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 8. Financial Statements and Supplementary Data.

ORUKA THERAPEUTICS, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Oruka Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Oruka Therapeutics, Inc. and its subsidiary (the "Company") as of December 31, 2025 and December 31, 2024, and the related consolidated statements of operations, of comprehensive loss, of convertible preferred stock and stockholders' equity and of cash flows for the year ended December 31, 2025 and for the period from February 6, 2024 (inception) to December 31, 2024, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and December 31, 2024, and the results of its operations and its cash flows for the year ended December 31, 2025 and for the period from February 6, 2024 (inception) to December 31, 2024 in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

External Research and Development Costs

As described in Note 2 to the consolidated financial statements, 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. As disclosed by management, the Company's research and development expense for the year ended December 31, 2025 was $100.6 million, $64.4 million of which relates to external research and development costs.

The principal consideration for our determination that performing procedures relating to external research and development costs is a critical audit matter is a high degree of auditor effort in performing procedures related to the Company's external research and development costs.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included, among others, testing external research and development costs, on a sample basis, by obtaining and agreeing the contractual terms of the agreement, amounts incurred to date, and estimates of work performed to date to the (i) underlying agreements with vendors engaged to conduct research and development; (ii) purchase orders; (iii) invoices received; (iv) underlying payments made for expenses incurred on the contracts; and (v) external confirmations or communications obtained by management from vendors.

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts
March 12, 2026

We have served as the Company's auditor since 2024.

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

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 46,935	$ 61,575
Marketable securities, current	290,109	314,073
Prepaid expenses and other current assets	6,813	1,221
Total current assets	343,857	376,869
Marketable securities, long-term	142,539	18,069
Property and equipment, net	288	162
Operating lease right-of-use assets	1,830	876
Other non-current assets	103	43
Total assets	$ 488,617	$ 396,019
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,155	$ 3,462
Accrued expenses and other current liabilities	10,591	3,346
Operating lease liability, current	619	213
Related party accounts payable and other current liabilities	9	6,022
Total current liabilities	15,374	13,043
Operating lease liability, non-current	1,313	755
Total liabilities	16,687	13,798
Commitments and contingencies (Note 15)		
Stockholders' equity:		
Series B non-voting convertible preferred stock, $0.001 par value; 251,504 shares authorized as of December 31, 2025 and 2024; 137,138 shares issued and outstanding as of December 31, 2025 and 2024	2,931	2,931
Common stock, $0.001 par value as of December 31, 2025 and 2024; 545,000,000 shares authorized as of December 31, 2025 and 2024, 48,722,309 and 37,440,510 shares issued and outstanding as of December 31, 2025 and 2024, respectively	49	37
Additional paid-in capital	657,561	463,018
Accumulated other comprehensive income (loss)	546	(41)
Accumulated deficit	(189,157)	(83,724)
Total stockholders' equity	471,930	382,221
Total liabilities and stockholders' equity	$ 488,617	$ 396,019

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

ORUKA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share data)

	Year Ended December 31, 2025	Period from February 6, 2024 (inception) to December 31, 2024
Operating expenses:		
Research and development[1]	$ 100,640	$ 75,060
General and administrative[2]	21,411	13,063
Total operating expenses	122,051	88,123
Loss from operations	(122,051)	(88,123)
Other income (expense):		
Interest income	16,630	5,863
Interest expense[3]	—	(1,468)
Other income (expense), net	(12)	4
Total other income, net	16,618	4,399
Net loss	$ (105,433)	$ (83,724)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.85)	$ (3.87)
Net loss per share attributable to Series A non-voting convertible preferred stockholders, basic and diluted	$ —	$ (3,873.25)
Net loss per share attributable to Series B non-voting convertible preferred stockholders, basic and diluted	$ (154.03)	$ (322.81)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	45,614,142	16,789,362
Weighted-average shares used in computing net loss per share attributable to Series A non-voting convertible preferred stockholders, basic and diluted	—	495
Weighted-average shares used in computing net loss per share attributable to Series B non-voting convertible preferred stockholders, basic and diluted	137,138	51,946

(1) Includes related party amounts of $17,129 and $42,640 for the year ended December 31, 2025 and for the period from February 6, 2024 (inception) to December 31, 2024, respectively

(2) Includes related party amounts of $139 and $1,364 for the year ended December 31, 2025 and for the period from February 6, 2024 (inception) to December 31, 2024, respectively

(3) Includes related party amounts of nil and $1,468 for the year ended December 31, 2025 and for the period from February 6, 2024 (inception) to December 31, 2024, respectively

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

ORUKA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands)

	Year Ended December 31, 2025	Period from February 6, 2024 (inception) to December 31, 2024
Net loss	$ (105,433)	$ (83,724)
Other comprehensive income (loss):		
Unrealized gains (losses) on marketable securities	587	(41)
Total comprehensive loss	$ (104,846)	$ (83,765)

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

ORUKA THERAPEUTICS, INC.
CONSOLIDATED STATEMENT OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY
(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 Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	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	—	—	—	—	—	—	—	—	—	—
Exchange of Series A convertible preferred stock for Series B non-voting convertible preferred stock upon the closing of the reverse capitalization	(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.	—	—	—	—	—	—	—	—	(20,504)	—	—	(20,504)
Issuance of common stock to former stockholders of ARCA biopharma, Inc. in connection with the closing of 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 2024 PIPE Financing	—	—	2,439	56,097	—	—	5,600,000	6	144,433	—	—	144,439
Issuance costs of 2024 PIPE Financing	—	—	—	(3,263)	—	—	—	—	(8,592)	—	—	(8,592)
Conversion of Series A non-voting convertible preferred stock to common stock	—	—	(2,439)	(52,834)	—	—	2,439,000	2	52,832	—	—	52,834
Issuance of common stock under employee stock purchase plan	—	—	—	—	—	—	2,960	—	53	—	—	53
Reclassification of the Paruka warrant from liability to equity	—	—	—	—	—	—	—	—	10,357	—	—	10,357

ORUKA THERAPEUTICS, INC.
CONSOLIDATED STATEMENT OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY — (Continued)
(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 Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Stock-based compensation expense	—	—	—	—	—	—	—	—	4,562	—	—	4,562
Unrealized losses on marketable securities	—	—	—	—	—	—	—	—	—	(41)	—	(41)
Net loss	—	—	—	—	—	—	—	—	—	—	(83,724)	(83,724)
Balances as of December 31, 2024	—	$ —	—	$ —	137,138	$ 2,931	37,440,510	$ 37	$ 463,018	$ (41)	$ (83,724)	$ 382,221
Issuance of common stock and pre-funded warrants in connection with the 2025 PIPE Financing	—	—	—	—	—	—	10,933,405	11	179,989	—	—	180,000
Issuance cost of the 2025 PIPE Financing	—	—	—	—	—	—	—	—	(10,356)	—	—	(10,356)
Issuance of common stock upon exercise of pre-funded warrants	—	—	—	—	—	—	325,000	1	(1)	—	—	—
Issuance of common stock upon exercise of stock options and employee warrants	—	—	—	—	—	—	36,022	—	294	—	—	294
Issuance of common stock under employee stock purchase plan	—	—	—	—	—	—	35,316	—	377	—	—	377
Cancellation of restricted stock awards	—	—	—	—	—	—	(47,944)	—	—	—	—	—
Reclassification of the Paruka warrant from liability to equity	—	—	—	—	—	—	—	—	10,065	—	—	10,065
Stock-based compensation expense	—	—	—	—	—	—	—	—	14,175	—	—	14,175
Unrealized gains on marketable securities	—	—	—	—	—	—	—	—	—	587	—	587
Net loss	—	—	—	—	—	—	—	—	—	—	(105,433)	(105,433)
Balances as of December 31, 2025	—	$ —	—	$ —	137,138	$ 2,931	48,722,309	$ 49	$ 657,561	$ 546	$ (189,157)	$ 471,930

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

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

	Year Ended December 31, 2025	Period from February 6, 2024 (inception) to December 31, 2024
Cash flows from operating activities:		
Net loss	$ (105,433)	$ (83,724)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	24,240	14,919
Net accretion of premiums and discounts on marketable securities	(5,003)	(2,245)
Non-cash interest expense	—	1,468
Non-cash lease expense	458	127
Depreciation expense	83	27
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(3,972)	(1,128)
Other non-current assets	(60)	(43)
Accounts payable	693	3,462
Accrued expenses and other current liabilities	7,245	3,292
Operating lease liability	(448)	(14)
Related party accounts payable and other current liabilities	(6,013)	6,022
Net cash used in operating activities	(88,210)	(57,837)
Cash flows from investing activities:		
Purchases of property and equipment	(209)	(189)
Purchases of marketable securities	(520,959)	(329,938)
Proceeds from maturities of marketable securities	424,423	—
Net cash used in investing activities	(96,745)	(330,127)
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 party, net of issuance costs paid	—	24,980
Proceeds from the Pre-Closing Financing, net	—	227,953
Proceeds from the PIPE Financings, net	169,644	188,681
Cash acquired in connection with the reverse recapitalization	—	4,940
Proceeds from issuance of common stock upon exercise of stock options and employee warrants and purchases under employee stock purchase plan	671	54
Net cash provided by financing activities	170,315	449,539
Net (decrease) increase in cash and cash equivalents	(14,640)	61,575
Cash and cash equivalents at beginning of period	61,575	—
Cash and cash equivalents at end of period	$ 46,935	$ 61,575
Supplemental disclosures of non-cash operating and financing activities:		
Operating lease liability arising from obtaining operating right-of-use asset	$ 1,412	$ 982
Assets acquired in connection with the reverse recapitalization	$ —	$ 114
Other liabilities assumed in connection with the reverse recapitalization	$ —	$ (54)
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
Conversion of Series A non-voting convertible preferred stock to common stock	$ —	$ 52,834
Reclassification of the Paruka warrant from liability to equity	$ 10,065	$ 10,357

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

1. Nature of the Business and Basis of Presentation

Background and Basis of Presentation

Oruka Therapeutics, Inc., together with its subsidiary (collectively, the "Company"), formerly known as ARCA biopharma, Inc. ("ARCA"), is a clinical-stage biopharmaceutical 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 novel monoclonal antibody therapeutics for psoriasis ("PsO") and other inflammatory and immunology ("I&I") indications.

The accompanying consolidated financial statements reflect the operations of the Company and its wholly-owned subsidiary. Intercompany balances and transactions have been eliminated in consolidation. The accompanying consolidated financial statements have been prepared in conformity with United States ("U.S.") generally accepted accounting principles ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

Reverse Recapitalization and Pre-Closing Financing, and Reverse Stock Split

On August 29, 2024 (the "Closing"), the Company completed the acquisition (the "Merger") of Pre-Merger Oruka pursuant to an Agreement and Plan of Merger and Reorganization, dated as of April 3, 2024 (the "Merger Agreement"). Following the transactions contemplated by the Merger Agreement, Pre-Merger Oruka merged with and into Atlas Merger Sub Corp., a wholly owned subsidiary of ARCA and following that, Pre-Merger Oruka then merged with and into Atlas Merger Sub II, LLC ("Second Merger Sub"), with Second Merger Sub being the surviving entity. Second Merger Sub changed its corporate name to "Oruka Therapeutics Operating Company, LLC". On August 29, 2024, the Company changed its name from "ARCA biopharma, Inc." to "Oruka Therapeutics, Inc." and the Company effected a 1-for-12 reverse stock split (the "Reverse Stock Split") of its common stock, par value $0.001 per share ("Company Common Stock"), which became effective on September 3, 2024. All references to common stock, options to purchase common stock, outstanding common stock warrants, common stock share data, per share data, Company Common Stock, and related information contained in the 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.

Immediately prior to the execution and delivery of the Merger Agreement, certain new and existing investors of Pre-Merger Oruka entered into a subscription agreement with Pre-Merger Oruka (that was subsequently amended and restated in July 2024, 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 9) 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 were recorded as a reduction to additional paid-in capital in the consolidated financial statements.

In connection with the Closing, the shares of Pre-Merger Oruka Common Stock were converted into shares of Company Common Stock and pre-funded warrants of Company Common Stock in accordance with the Exchange Ratio (as defined below and determined by the terms of the Merger Agreement). Moreover, as part of the Closing, (i) then-issued and outstanding shares 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") was converted into the

1. Nature of the Business and Basis of Presentation (cont.)

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 after the Reverse Stock Split, (iii) each outstanding option to purchase Pre-Merger Oruka Common Stock was converted into an option to purchase shares of Company Common Stock, and (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.

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 owned a substantial majority of the voting rights in the combined company; (ii) Pre-Merger Oruka's largest stockholders retained 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: (a) the Merger was treated as the equivalent of Pre-Merger Oruka issuing stock to acquire the net assets of ARCA, and (b) the reported historical operating results of the combined company prior to the Merger are those of Pre-Merger Oruka. As part of the reverse recapitalization, the Company acquired a cash balance of $4.94 million from ARCA. Additional information regarding the Merger is included in Note 3.

Liquidity

As of December 31, 2025, the Company had cash, cash equivalents, and marketable securities of $479.6 million and an accumulated deficit of $189.2 million. 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 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 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 consolidated financial statements and the reported amounts of income and expenses during the reporting periods. Significant estimates and assumptions reflected within these 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.

2. Summary of Significant Accounting Policies (cont.)

Concentrations of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash, cash equivalents and marketable securities. The Company's investment policy limits investments to high credit quality securities issued by the U.S. government, U.S. government-sponsored agencies, highly rated banks, and corporate issuers, subject to certain concentration limits and restrictions on maturities. The Company's cash, cash equivalents and marketable securities are held by financial institutions that management believes are of high credit quality. The financial instruments that potentially subject the Company to a concentration of credit risk consist principally of cash deposits. Accounts at the Company's U.S. banking institution are insured by the Federal Deposit Insurance Corporation ("FDIC") up to $250,000 per depositor. As of December 31, 2025, the balance at the Company's U.S. banking institution exceeded the FDIC limits. The Company has not experienced any losses on its deposits of cash and cash equivalents and its accounts are monitored by management to mitigate risk. The Company is exposed to credit risk in the event of default by the financial institutions holding its cash and cash equivalents, and bond issuers.

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 14).

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, U. S. treasury securities, U.S. government agency securities, and debt securities and are stated at fair value.

Marketable Securities

The Company invests in marketable securities, primarily securities issued by the U.S. government and its agencies, commercial paper and corporate debt securities. The Company's marketable securities are classified as available-for-sale and reported at fair value, with unrealized gains and losses included as a component of accumulated other comprehensive loss.

For available-for-sale debt securities in an unrealized loss position, the Company first assesses whether it intends to sell, or it is more likely than not that it will be required to sell the security before recovery of its amortized cost basis. If either of the criteria regarding intent or requirement to sell is met, the security's amortized cost basis is written down to fair value and recognized in other income (expense) in the results of operations. For available-for-sale debt securities that do not meet the aforementioned criteria, the Company evaluates whether the decline in fair value has resulted from credit losses or other factors. In making this assessment, management considers the extent to which fair value is less than amortized cost, any changes to the rating of the security by a rating agency, and adverse conditions specifically related to the security, among other factors. If this assessment indicates that a credit loss exists, an allowance is recorded for the difference between the present value of cash flows expected to be collected and the amortized cost basis of the security. Impairment losses attributable to credit loss factors are charged against the allowance when management believes an available-for-sale security is uncollectible or when either of the criteria regarding intent or requirement to sell is met.

Any unrealized losses from declines in fair value below the amortized cost basis as a result of non-credit loss factors are recognized as a component of accumulated other comprehensive loss, net of unrealized gains. Realized gains and losses and declines in fair value, if any, on available-for-sale securities are included in other income, net, in the results of operations.

2. Summary of Significant Accounting Policies (cont.)

Marketable securities with stated maturities of greater than three months from the date of purchase but less than one year from the consolidated balance sheet date are classified as current, while marketable securities with maturities in one year or beyond one year from the consolidated balance sheet date are classified as long-term. The cost of securities sold is determined using the specific-identification method. Interest earned and adjustments for the amortization of premiums and discounts on investments are included in interest income on the consolidated statements of operations and comprehensive loss.

Debt Issuance Costs

Debt issuance costs incurred in connection with the Convertible Note (see Note 9) 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. At the effective time of the Merger the Convertible Note was converted to common stock and is no longer on the balance sheet as of December 31, 2025.

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 and marketable securities are carried at fair value, determined according to the fair value hierarchy described above (see Note 6). 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 is computed using the straight-line method over the estimated useful lives of the assets, ranging from three to five years. Leasehold improvements are amortized over the shorter of the lease term or the estimated useful lives of the assets. Maintenance and repairs are charged to expense as incurred. When assets are retired or otherwise disposed of, the cost and accumulated depreciation are removed from the consolidated balance sheet and any resulting gain or loss is reflected in operations in the period realized.

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 on the Company's 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.

2. Summary of Significant Accounting Policies (cont.)

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 on its 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 2024 PIPE Financing (see Note 4) the Company issued Company Series A Preferred Stock, and has classified the Company Series A Preferred Stock outside of stockholders' equity on the Company's consolidated balance sheet because the holders of such stock have certain rights (see Note 10) 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. In November 2024, the Company Series A Preferred Stock shares were converted to common stock, and as of December 31, 2025 and December 31, 2024, there were no shares of Company Series A Preferred Stock outstanding.

Note Payable to Related Party

The Company accounted for the Convertible Note (as defined in Note 9) 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 9) and were accounted for as interest expense in other income (expenses) within the consolidated statements of operations 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 14).

The Company accrues for expenses resulting from obligations under its antibody discovery and option agreements (the "Option Agreements") (see Note 14), 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 December 31, 2025 and December 31, 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.

2. Summary of Significant Accounting Policies (cont.)

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 December 31, 2025, the Company has two operating leases 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 consolidated statements of operations on a straight-line basis over the lease term and are not recorded on its 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 as a single reportable and operating segment. Its Chief Executive Officer, serving as the Chief Operating Decision Maker ("CODM"), oversees operations on an aggregated basis to allocate resources effectively. In assessing the Company's financial performance, the CODM regularly reviews total operating expenses and consolidated net loss.

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 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 December 31, 2025 and 2024, no liabilities were recorded for loss contingencies (see Note 15).

2. Summary of Significant Accounting Policies (cont.)

Stock-Based Compensation

The Company estimates the fair value of its stock awards using the Black-Scholes option pricing model, which uses as inputs the fair value of the Company's common stock, and certain management estimates, including the expected stock price volatility, the expected term of the award, the risk-free interest rate, and expected dividends. Expected volatility is calculated based on reported volatility data for a representative group of publicly traded companies for which historical information is available. The Company selects companies with comparable characteristics with historical share price information that approximates the expected term of the equity-based awards. The Company computes the historical volatility data using the daily closing prices for the selected companies' shares during the equivalent period that approximates the calculated expected term of the stock options. The Company will continue to apply this method until a sufficient amount of historical information regarding the volatility of its stock price becomes available. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant, commensurate with the expected term assumption. For employee and non-employee awards (except the Paruka warrant) the Company uses the simplified method, under which the expected term is presumed to be the midpoint between the vesting date and the end of the contractual term. The Company utilizes this method due to lack of historical exercise data. For the Paruka warrant, the contractual term is used for the expected term. The expected dividend yield is assumed to be zero as the Company has no current plans to pay any dividends on common stock.

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 consolidated statements of operations 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, as applicable.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity that result from transactions and events other than those with stockholders. The Company's unrealized gains and losses on marketable securities represent the only component of other comprehensive loss that is excluded from the reported net loss and that is presented in the consolidated statements of comprehensive loss.

2. Summary of Significant Accounting Policies (cont.)

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 10 — 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.

Other income (expense), net

Other income (expense), net, consists of interest earned on the Company's cash, cash equivalents, and marketable securities; interest expense on the convertible note from a related party, and foreign currency transactions gains and losses.

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 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 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 December 31, 2025.

2. Summary of Significant Accounting Policies (cont.)

Recently Adopted Accounting Pronouncements

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 adopted ASU 2023-09 in 2025 and applied the update retrospectively for the period from February 6, 2024 (inception) to December 31, 2024, and the impact of the adoption of this update was not material to the Company's consolidated financial position and results of operations since the update requires only enhancements of existing income tax disclosures. The additional required disclosures have been included in Note 13.

Recently Issued Accounting Pronouncements

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):

	August 29, 2024
Cash and cash equivalents	$ 4,940
Other current assets	114
Accrued liabilities	(54)
Net assets acquired	$ 5,000

4. PIPE Financings

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

Pursuant to the 2024 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 share of Company Series A Preferred Stock was 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 $11.9 million). In November 2024, the 2,439 shares of the Company Series A Preferred Stock were converted to 2,439,000 shares of Company Common Stock.

4. PIPE Financings (cont.)

On September 17, 2025, the Company entered into a Securities Purchase Agreement (the "2025 Securities Purchase Agreement") for a private placement (the "2025 PIPE Financing") with certain institutional and accredited investors. The closing of the 2025 PIPE Financing occurred on September 19, 2025.

Pursuant to the 2025 Securities Purchase Agreement, the investors purchased an aggregate of 10,933,405 shares of Company Common Stock at a purchase price of $15.00 per share, and pre-funded warrants to purchase an aggregate of 1,066,666 shares of Company Common Stock at a purchase price of $14.999 per pre-funded warrant, for aggregate net proceeds of approximately $169.6 million (net of issuance costs of $10.4 million).

5. ATM Offering

On October 3, 2025, the Company entered into a Sales Agreement with TD Securities (USA) LLC (the "Sales Agreement"), as its sales agent, pursuant to which the Company may issue and sell, from time to time, shares of the Company Common Stock for aggregate gross proceeds of up to $200.0 million under an at-the-market ("ATM") offering program. The Company is not obligated to make any sales of shares under the Sales Agreement. No securities were sold under the ATM offering program during the year ended December 31, 2025. Subsequent to the year end, the Company issued and sold an aggregate of 1,167,895 shares of Company Common Stock pursuant to the ATM offering program at an average price per share of $33.99 for total net proceeds of $38.9 million after deducting sales agents' commissions.

6. Fair Value Measurements

The following tables present the Company's fair value hierarchy for financial assets measured as of December 31, 2025 and 2024 (in thousands):

	December 31, 2025			
	Level 1	Level 2	Level 3	Total
Cash equivalents				
Money market funds	$ 30,268	$ —	$ —	$ 30,268
Commercial papers	—	14,483	—	14,483
Total cash equivalents	30,268	14,483	—	44,751
Marketable securities				
Marketable securities, current				
U.S. treasury securities	—	195,915	—	195,915
U.S. government agency securities	—	28,757	—	28,757
Commercial papers	—	21,241	—	21,241
Corporate debt securities	—	44,196	—	44,196
Total marketable securities, current	—	290,109	—	290,109
Marketable securities, long-term				
U.S. treasury securities	—	75,730	—	75,730
Corporate debt securities	—	54,998	—	54,998
U.S. government agency securities	—	11,811	—	11,811
Total marketable securities, long-term	—	142,539	—	142,539
Total cash equivalents and marketable securities	$ 30,268	$ 447,131	$ —	$ 477,399

6. Fair Value Measurements (cont.)

	December 31, 2024			
	Level 1	Level 2	Level 3	Total
Cash equivalents				
Money market funds	$ 6,350	$ —	$ —	$ 6,350
U.S. treasury securities	—	19,660	—	19,660
U.S. government agency securities	—	3,988	—	3,988
Commercial papers	—	22,177	—	22,177
Total cash equivalents	6,350	45,825	—	52,175
Marketable securities				
Marketable securities, current				
U.S. treasury securities	—	190,792	—	190,792
U.S. government agency securities	—	12,966	—	12,966
Commercial papers	—	34,811	—	34,811
Corporate debt securities	—	75,504	—	75,504
Total marketable securities, current	—	314,073	—	314,073
Marketable securities, long-term				
U.S. treasury securities	—	13,607	—	13,607
U.S. government agency securities	—	4,462	—	4,462
Total marketable securities, long-term	—	18,069	—	18,069
Total cash equivalents and marketable securities	$ 6,350	$ 377,967	$ —	$ 384,317

There were no transfers in or out of Level 3 during the year ended December 31, 2025, and the period from February 6, 2024 (inception) to December 31, 2024.

7. Cash Equivalents and Marketable Securities

Cash equivalents and marketable securities, which are classified as available-for-sale, consisted of the following as of December 31, 2025 and 2024 (in thousands):

	December 31, 2025			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash equivalents				
Money market funds	$ 30,268	$ —	$ —	$ 30,268
Commercial papers	14,484	—	(1)	14,483
Total cash equivalents	44,752	—	(1)	44,751
Marketable securities				
Marketable securities, current				
U.S. treasury securities	195,607	308	—	195,915
U.S. government agency securities	28,724	33	—	28,757
Commercial papers	21,239	2	—	21,241
Corporate debt securities	44,173	26	(3)	44,196
Total marketable securities, current	289,743	369	(3)	290,109
Marketable securities, long-term				
U.S. treasury securities	75,612	118	—	75,730
Corporate debt securities	54,949	55	(6)	54,998
U.S. government agency securities	11,797	14	—	11,811
Total marketable securities, long-term	142,358	187	(6)	142,539
Total cash equivalents and marketable securities	$ 476,853	$ 556	$ (10)	$ 477,399

7. Cash Equivalents and Marketable Securities (cont.)

	December 31, 2024			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash equivalents				
Money market funds	$ 6,350	$ —	$ —	$ 6,350
U.S. treasury securities	19,656	4	—	19,660
U.S. government agency securities	3,988	—	—	3,988
Commercial papers	22,180	—	(3)	22,177
Total cash equivalents	52,174	4	(3)	52,175
Marketable securities				
Marketable securities, current				
U.S. treasury securities	190,748	55	(11)	190,792
U.S. government agency securities	12,967	1	(2)	12,966
Commercial papers	34,808	3	—	34,811
Corporate debt securities	75,537	7	(40)	75,504
Total marketable securities, current	314,060	66	(53)	314,073
Marketable securities, long-term				
U.S. treasury securities	13,639	—	(32)	13,607
U.S. government agency securities	4,485	—	(23)	4,462
Total marketable securities, long-term	18,124	—	(55)	18,069
Total cash equivalents and marketable securities	$ 384,358	$ 70	$ (111)	$ 384,317

The following table summarizes the available-for-sale securities in an unrealized loss position, aggregated by major security type and length of time in a continuous unrealized loss position, for which an allowance for credit losses was not recorded as of December 31, 2025 and 2024 (in thousands):

	December 31, 2025					
	Less than 12 months		12 months or longer		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Cash equivalents						
Commercial papers	$ 14,483	$ (1)	$ —	$ —	$ 14,483	$ (1)
Marketable securities						
Marketable securities, current						
Corporate debt securities	8,771	(3)	—	—	8,771	(3)
Marketable securities, long-term						
Corporate debt securities	6,143	(6)	—	—	6,143	(6)
Total	$ 29,397	$ (10)	$ —	$ —	$ 29,397	$ (10)

7. Cash Equivalents and Marketable Securities (cont.)

	December 31, 2024					
	Less than 12 months		12 months or longer		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Cash equivalents						
Commercial papers	$ 18,199	$ (3)	$ —	$ —	$ 18,199	$ (3)
Marketable securities						
Marketable securities, current						
U.S. treasury securities	49,904	(11)	—	—	49,904	(11)
U.S. government agency securities	4,713	(2)	—	—	4,713	(2)
Corporate debt securities	39,468	(40)	—	—	39,468	(40)
Marketable securities, long-term					—	—
U.S. treasury securities	13,607	(32)	—	—	13,607	(32)
U.S. government agency securities	4,462	(23)	—	—	4,462	(23)
Total	$ 130,353	$ (111)	$ —	$ —	$ 130,353	$ (111)

The Company evaluated its securities for credit losses and considered the decline in market value to be primarily attributable to current economic and market conditions and not to a credit loss or other factors. Additionally, the Company does not intend to sell the securities in an unrealized loss position and it is not more likely than not that the Company will be required to sell the securities before recovery of the unamortized cost basis, which may be at maturity. There were no material realized gains or realized losses on marketable securities for the period presented. Given the Company's intent and ability to hold such securities until recovery, and the lack of significant change in credit risk of these investments, the Company does not consider these marketable securities to be impaired as of December 31, 2025 and 2024. As of December 31, 2025 and 2024, the Company did not record an allowance for credit losses.

The following table summarizes the contractual maturities of the Company's marketable securities at estimated fair value (in thousands):

	December 31, 2025	December 31, 2024
Due in one year or less	$ 290,109	$ 314,073
Due in 1-2 years	142,539	18,069
Total	$ 432,648	$ 332,142

8. Accrued Expenses and Other Current Liabilities

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

	December 31, 2025	December 31, 2024
Accrued employee compensation and benefits	$ 5,266	$ 2,041
Accrued research and development	4,384	1,084
Accrued professional and consulting	941	221
Total	$ 10,591	$ 3,346

9. Note Payable with Related Party

In March 2024, Pre-Merger Oruka entered into a Series A Preferred Stock and Convertible Note Purchase Agreement (the "Purchase Agreement") with Fairmount Healthcare Fund II, L.P. ("Fairmount"), whereby Pre-Merger Oruka 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. 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.

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 consolidated balance sheet and were being amortized as interest expense over the term of the Convertible Note using the effective interest method. For the year ended December 31, 2025 and the period from February 6, 2024 (inception) to December 31, 2024, the Company recognized interest expenses related to the Convertible Note of nil and $1.5 million, respectively, which includes non-cash interest expense related to the amortization of debt issuance. As of December 31, 2025 and 2024, the Convertible Note was not outstanding.

10. 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 Closing, there were 5,522,207 pre-funded warrants outstanding and were exercisable for 5,522,207 shares of the Company Common Stock at an exercise price of $0.01 per share. The Company issued 25,014 shares of Company Common Stock on net exercises of 25,024 pre-funded warrants during the year ended December 31, 2025.

In September 2024, in connection with the 2024 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 Company issued 299,986 shares of Company Common Stock on net exercises of 300,000 pre-funded warrants during the year ended December 31, 2025.

In September 2025, in connection with the 2025 PIPE Financing, the Company issued and sold 1,066,666 pre-funded warrants, at a purchase price of $14.999 per warrant, exercisable for 1,066,666 shares of Company Common Stock at an exercise price of $0.001 per share.

10. Convertible Preferred Stock and Stockholders' Equity (cont.)

The pre-funded warrants were recorded as a component of stockholders' equity within additional paid-in-capital and have no expiration date. Collectively, 6,943,849 and 6,202,207 pre-funded warrants were outstanding as of December 31, 2025 and 2024, respectively.

Employee Warrants

The Subscription Agreement provided for, among other things, the issuance of warrants to certain of Pre-Merger Oruka's employees and directors immediately prior to the Closing. During the period from February 6, 2024 (inception) to December 31, 2024, 3,054,358 employee warrants were issued at an exercise price of $7.80 per warrant. These warrants vest over a period of four years. Per the terms of the Employee Warrant Agreement, the holders of the Company's 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 warrants on a straight-line basis over the requisite service period, which is the period in which the related services are received. During the year ended December 31, 2025, 19,570 warrants were exercised. No employee warrants were exercised during the period from February 6, 2024 (inception) to December 31, 2024. As of December 31, 2025 and 2024, 3,029,510 and 3,054,358 warrants, respectively, were 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, 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 Closing, the Pre-Merger Oruka Series A Preferred Stock converted to 137,138 shares of Company Series B Preferred Stock.

In September 2024, in connection with the 2024 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. In November 2024, the 2,439 shares of the Company Series A Preferred Stock were converted to 2,439,000 shares of Company Common Stock. As of December 31, 2025 and 2024, there are no outstanding shares of Company Series A Preferred Stock.

As of December 31, 2025 and 2024, convertible preferred stock consisted of the following (in thousands, except share data):

	December 31, 2025			
	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Common Stock Issuable Upon Conversion
Company Series B Preferred Stock.	251,504	137,138	$ 2,931	11,428,149

	December 31, 2024			
	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Common Stock Issuable Upon Conversion
Company Series B Preferred Stock.	251,504	137,138	$ 2,931	11,428,149

10. Convertible Preferred Stock and Stockholders' Equity (cont.)

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 were 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 did 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, on issuance, resulted in the Company Series A Preferred Stock being classified outside of stockholders' equity on the Company's consolidated balance sheet. Following the Stockholder Approval in November 2024, each share of Company Series A Preferred Stock was automatically converted into 1,000 shares of Company Common Stock.

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 each of December 31, 2025 and 2024, each outstanding share of Company Series B Preferred Stock was convertible into common stock at a ratio of approximately 83.3332:1.

Paruka Warrant

On December 31, 2024, the Company settled its 2024 obligations under the Paruka Warrant Obligation (defined below) by issuing Paruka a warrant to purchase 596,930 shares of Company Common Stock at an exercise price of $19.39 per share. On December 12, 2025, the Company settled its 2025 obligations under the Paruka Warrant Obligation (defined below) by issuing Paruka a warrant to purchase 375,000 shares of Company Common Stock at an exercise price of $30.18 per share. The warrants have a term of 10 years, are fully vested, and are exercisable in part or full at any time during the term of the warrant. As of December 31, 2025 and 2024, the warrants issued under the Paruka Warrant Obligation are outstanding and unexercised. See Note 11 for additional information on the Paruka Warrant Obligation.

Common Stock

The Certificate of Incorporation provides for 545,000,000 authorized shares of Company Common Stock as of each of December 31, 2025 and 2024. As of December 31, 2025, 48,722,309 shares of Company Common Stock were issued and outstanding, including 2,159,609 shares of RSAs issued and outstanding. As of December 31, 2024, 37,440,510 shares of Company Common Stock were issued and outstanding, including 2,207,553 shares of RSAs issued and outstanding.

10. Convertible Preferred Stock and Stockholders' Equity (cont.)

As of December 31, 2025 and 2024, the Company had common stock reserved for future issuance as follows:

	December 31, 2025	December 31, 2024
Shares issuable on conversion of Company Series B Preferred Stock	11,428,149	11,428,149
Shares issuable upon exercise of pre-funded warrants	6,943,849	6,202,207
Shares issuable upon exercise of warrants under the Paruka Warrant Obligation	971,930	596,930
Outstanding and issued stock options	3,950,958	1,567,760
Outstanding and issued employee warrants	3,029,510	3,054,358
Shares available for grant under 2024 Stock Incentive Plan	4,600,217	4,246,324
Shares available for grant under 2024 Employee Stock Purchase Plan	975,922	460,529
Total shares of common stock reserved	31,900,535	27,556,257

11. 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 two non-employee stock options were granted with vesting terms less than four years. As of December 31, 2025, and 2024, 1,167,826 shares and 1,179,193 shares, respectively, were subject to options outstanding under the 2024 Plan and will become available under the 2024 Stock Incentive Plan (defined below) to the extent the options are forfeited or lapse unexercised.

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 was 4,634,891 shares of Company Common Stock. 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. An additional 2,753,543 shares and 3,354,715 shares became available for issuance under the 2024 Stock Plan on January 1, 2025 and 2026, respectively, as a result of the annual increase pursuant to the evergreen provision. Current or prospective employees, officers, non-employee directors, and other independent service providers of the Company and its subsidiary are eligible to participate in the 2024 Stock Plan.

As of December 31, 2025, 7,383,349 shares were reserved for issuance under the 2024 Stock Plan, of which 4,600,217 shares were available for future grant and 2,783,132 shares were subject to outstanding options. As of December 31, 2024, 4,634,891 shares were reserved for issuance under the 2024 Stock Plan, of which 4,246,324 shares were available for future grant and 388,567 shares were subject to outstanding options.

11. Stock-Based Compensation (cont.)

2024 Employee Stock Purchase Plan

The 2024 Employee Stock Purchase Plan (the "ESPP") became effective in August 2024, at which time 463,489 shares of Company Common Stock were reserved for issuance. Eligible employees may purchase shares of Company Common Stock under the ESPP at 85% of the lower of the fair market value of the Company Common Stock as of the first or the last day of each offering period. Employees are limited to contributing 15% of the employee's eligible compensation and may not purchase more than $25,000 of stock during any calendar year. The ESPP will terminate ten years from the first purchase date under the plan, unless terminated earlier by the board of directors.

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. An additional 550,709 shares and nil shares became available for issuance under the ESPP on January 1, 2025 and 2026, respectively, as a result of the annual increase pursuant to the evergreen provision.

The Company issued 35,316 and 2,960 shares during the year ended December 31, 2025 and for the period from February 6, 2024 (inception) to December 31, 2024, respectively, out of the ESPP. As of December 31, 2025 and 2024, there were 975,922 and 460,529 shares, respectively, of Company Common Stock available in the pool for future issuances.

For the year ended December 31, 2025 and for the period from February 6, 2024 (inception) to December 31, 2024, stock-based compensation expenses related to the ESPP were $0.2 million and less than $0.1 million, respectively.

Stock Option Valuation

The following table summarizes the weighted-average assumptions used in calculating the fair value of the awards for the year ended December 31, 2025 and the period from February 6, 2024 (inception) to December 31, 2024:

	Year Ended December 31, 2025	Period from February 6, 2024 (inception) to December 31, 2024
Expected term (in years)	6.0	6.1
Expected volatility	95.2%	100.21%
Risk-free interest rate	4.32%	4.26%
Expected dividend yield	—	—

11. Stock-Based Compensation (cont.)

Stock Option Activity

The following table summarizes the stock option activities under the 2024 Plan and 2024 Stock Plan for the year ended December 31, 2025:

	Number of Stock Options Outstanding	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in Thousands)
Balance as of December 31, 2024	1,567,760	$ 11.39	9.4	$ 15,470
Granted	2,440,400	$ 13.35		
Exercised	(16,452)	$ 8.59		
Canceled/forfeited	(40,750)	$ 11.09		
Balance as of December 31, 2025	3,950,958	$ 12.61	8.9	$ 69,966
Vested and expected to vest, December 31, 2025	3,950,958	$ 12.61	8.9	$ 69,966
Exercisable, December 31, 2025	972,898	$ 10.75	8.6	$ 19,029

The weighted average grant-date fair value per share of stock options granted during the year ended December 31, 2025 and the period from February 6, 2024 (inception) to December 31, 2024 was $10.49 and $9.12 per share, respectively.

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. The total intrinsic value of the options exercised during the year ended December 31, 2025 and for the period from February 6, 2024 (inception) to December 31, 2024 was $0.3 million and nil, respectively.

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. For each of the year ended December 31, 2025 and the period February 6, 2024 (inception) to December 31, 2024, stock-based compensation expenses related to RSAs were less than $0.1 million.

The following table summarizes the RSA activity for the year ended December 31, 2025:

	Number of RSAs	Weighted Average Grant Date Fair Value
Unvested balance as of January 1, 2025	2,207,553	$ —
Granted	—	$ —
Vested	(1,010,020)	$ —
Forfeited	(47,944)	$ —
Unvested balance as of December 31, 2025	1,149,589	$ —

11. Stock-Based Compensation (cont.)

The fair value of restricted stock awards that vested during the year ended December 31, 2025 was $14.0 million.

Option Agreements and the Paruka Warrant Obligation

As part of the Option Agreements, the Company granted 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, or based upon the agreed number of warrants as disclosed in the Warrant Agreement, with an exercise price equal to the fair market value of the underlying shares on the grant date (the "Paruka Warrant Obligation").

The grant dates for the issuance of warrants were 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 Company determined that the 2024 and 2025 grants are two separate grants, as there would be no obligation for the 2025 grant had the Company exercised or terminated all of the options under the Option Agreements prior to December 31, 2024. 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, a liability related to the Paruka Warrant Obligation was recorded during the 2024 and 2025 interim periods. The liability is adjusted to fair value at the end of each interim reporting period, with changes in fair value recorded in the consolidated statements of operations as stock-based compensation expenses under research and development expenses.

The Company settled its 2024 and 2025 obligations under the Paruka Warrant Obligation by issuing Paruka 596,930 and 375,000 warrants, respectively, to purchase the Company Common Stock at an exercise price per share per warrant of $19.39 and $30.18, respectively. For the year ended December 31, 2025 and for the period from February 6 (inception) to December 31, 2024, $10.1 million and $10.4 million, respectively, were recognized as stock-based compensation expenses related to the Paruka Warrant obligation. On issuance of the warrants to Paruka, the fair value of the warrants was reclassified from liability to equity on the consolidated balance sheet as of December 31, 2025 and 2024.

The following table summarizes the assumptions used in calculating the fair value of the Paruka Warrant Obligation for the year ended December 31, 2025 and the period from February 6, 2024 (inception) to December 31, 2024:

	Year Ended December 31, 2025	Period from February 6, 2024 (inception) to December 31, 2024
Expected term (in years)	10.0	10.0
Expected volatility	94.08%	95.08%
Risk-free interest rate	4.19%	4.58%
Expected dividend yield	—	—

As of December 31, 2025, the unamortized expense related to Paruka Warrant Obligation was nil.

Employee Warrants

As stated above, in July 2024, the Subscription Agreement was amended and restated, among other things, for employee warrants to be issued to certain Pre-Merger Oruka employees and directors prior to the Closing. During the period from February 6, 2024 (inception) to December 31, 2024, the Company issued 3,054,358 warrants at an exercise price of $7.80 per warrant, which are accounted as equity in the consolidated financial statements. The employee warrants were subject to performance and service based vesting requirements and upon completion of the Merger the performance-based requirements had been achieved.

11. Stock-Based Compensation (cont.)

The following table summarizes the employee warrant activity for the period during the year ended December 31, 2025:

	Number of Employee Warrants Outstanding	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in Thousands)
Balance as of December 31, 2024	3,054,358	$ 7.80	9.5	$ 35,400
Granted	—	$ —		
Exercised	(19,570)	$ 7.80		
Canceled/forfeited	(5,278)	$ 7.80		
Balance as of December 31, 2025	3,029,510	$ 7.80	8.5	$ 68,194
Vested and expected to vest, December 31, 2025	3,029,510	$ 7.80	8.5	$ 68,194
Exercisable, December 31, 2025	1,221,338	$ 7.80	8.5	$ 27,492

No employee warrants were granted during the year ended December 31, 2025. The weighted average grant-date fair value per share of the employee warrants granted during the period from February 6, 2024 (inception) to December 31, 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 warrants. The total intrinsic value of the employee warrants exercised during the year ended December 31, 2025 and for the period from February 6, 2024 (inception) to December 31, 2024 was $0.4 million and nil, respectively.

The following table summarizes the weighted-average assumptions used in calculating the fair value of the warrants for the period from February 6, 2024 (inception) to December 31, 2024:

	Period from February 6, 2024 (inception) to December 31, 2024
Expected term (in years)	6.1
Expected volatility	99.02%
Risk-free interest rate	4.15%
Expected dividend yield	—

Stock-Based Compensation Expense

The following table summarizes the classification of the Company's stock-based compensation expense in the consolidated statements of operations (in thousands):

	Year Ended December 31, 2025	Period from February 6, 2024 (inception) to December 31, 2024
Research and development	$ 17,019	$ 11,992
General and administrative	7,221	2,927
Total	$ 24,240	$ 14,919

11. Stock-Based Compensation (cont.)

As of December 31, 2025, total unrecognized compensation cost related to the unvested stock options was $29.1 million, which is expected to be recognized over a weighted average period of approximately 2.9 years.

As of December 31, 2025, 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 2.1 years.

As of December 31, 2025, the unrecognized compensation cost related to the employee warrants was $11.0 million, which is expected to be recognized over a weighted average period of 2.3 years.

The following table summarizes the award types of the Company's stock-based compensation expense in the consolidated statements of operations (in thousands):

	Year Ended December 31, 2025	Period from February 6, 2024 (inception) to December 31, 2024
Paruka Warrant Obligation	$ 10,065	$ 10,357
Employee warrants	5,185	2,899
Stock options	8,805	1,626
Employee stock purchase plan	185	37
Total	$ 24,240	$ 14,919

12. Segment Disclosures

The Company operates and manages its business activities on a consolidated basis and operates in one reportable segment.

The Company operates as a single reportable and operating segment. Its Chief Executive Officer, serving as the Chief Operating Decision Maker ("CODM"), oversees operations on an aggregated basis to allocate resources effectively. In assessing the Company's financial performance, the CODM regularly reviews total operating expenses and consolidated net loss.

The measure of segment assets is reported on the balance sheet as total consolidated assets. The Company's long-lived assets consist primarily of property and equipment, net. As of December 31, 2025 all of long-lived assets were in the U.S.

12. Segment Disclosures (cont.)

The table summarizes the segment loss from operations, including significant segment expenses (in thousands):

	Year Ended December 31, 2025	Period from February 6, 2024 (inception) to December 31, 2024
Research and development personnel-related (excluding stock-based compensation)	$ 14,957	$ 3,959
General and administrative personnel-related (excluding stock-based compensation)	7,811	5,054
Research and development stock-based compensation	17,019	11,992
General and administrative stock-based compensation	7,221	2,927
External research and development	64,378	57,680
Other research and development	4,286	1,429
General and administrative, excluding personnel-related and stock-based compensation	6,379	5,082
Total operating expenses	122,051	88,123
Loss from operations	$ (122,051)	$ (88,123)

13. Income Taxes

No provision for income taxes was recorded for the year ended December 31, 2025 and for the period from February 6, 2024 (inception) to December 31, 2024.

The following table summarizes the loss before income tax expense by jurisdiction for the periods indicated (in thousands):

	Year Ended December 31, 2025	Period from February 6, 2024 (inception) to December 31, 2024
Domestic	$ (105,433)	$ (83,724)
Foreign	—	—
Loss before income tax expense	$ (105,433)	$ (83,724)

13. Income Taxes (cont.)

For the year ended December 31, 2025 and for the period from February 6, 2024 (inception) to December 31, 2024, the Company recognized no provision or benefit from income taxes. The difference between the Company's provision for income taxes and the amounts computed by applying the statutory federal income tax rate to income before income taxes is as follows (amounts in thousands):

	Year Ended December 31, 2025		Period from February 6, 2024 (inception) to December 31, 2024	
	Amount	Percent	Amount	Percent
Tax benefit derived by applying the federal statutory rate to loss before income taxes	$ (22,141)	(21.00)%	$ (17,582)	(21.00)%
Nontaxable or nondeductible items	54	0.05	76	0.09
Credits				
Research and development credits	(2,109)	(2.00)	(2,840)	(3.39)
Other	949	0.90	(731)	(0.87)
Worldwide changes in unrecognized tax benefits	(91)	(0.09)	—	0.00
Change in the valuation allowance	23,338	22.14	21,077	25.17
Income tax (benefit) expense	$ —	0.00%	$ —	0.00%

The components of the deferred tax assets and liabilities consist of the following (in thousands):

	December 31, 2025	December 31, 2024
Deferred tax assets		
Net operating loss carryforwards	$ 6,398	$ 2,260
Research and development credits	5,372	3,080
Stock-based compensation	7,827	3,063
Accruals and other	1,083	424
Lease liability	448	203
Intangibles	2,943	1,477
Capitalized R&D expenses	25,069	10,994
Total deferred tax assets	49,140	21,501
Deferred tax liabilities		
Right-of-use asset	(424)	(184)
Total deferred tax liabilities	(424)	(184)
Valuation allowance	(48,716)	(21,317)
Deferred tax assets, net	$ —	$ —

The Company has established a full federal and state valuation allowance equal to the net deferred tax assets due to uncertainties regarding the realization of the deferred tax asset based on the Company's lack of earnings history. The valuation allowance increased by $27.4 million and $21.3 million, respectively during the year ended December 31, 2025 and the period from February 6, 2024 (inception) to December 31, 2024, primarily due to continuing loss from operations.

13. Income Taxes (cont.)

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in thousands):

	Year Ended December 31, 2025	Period from February 6, 2024 (inception) to December 31, 2024
Beginning balance	$ 21,317	$ —
Change in valuation allowance	27,399	21,317
Ending balance	$ 48,716	$ 21,317

As of December 31, 2025 and 2024, the Company had U.S. net operating loss carryforwards ("NOL") of $28.2 million and $10.8 million, respectively. The federal NOL carryforwards do not expire and can be utilized to offset up to 80% of the taxable income in any tax year. As of December 31, 2025 and 2024, the Company also had state NOL carryforwards of $7.5 million and nil, respectively. The state NOL carryforwards will expire starting in 2044, if not utilized.

For the year ended December 31, 2025, the Company had federal tax credit carryforwards and state tax credit carryforwards of $6.7 million and $0.5 million, respectively. For the period from February 6, 2024 (inception) to December 31, 2024 the Company had federal tax credit carryforwards and state tax credit carryforwards of $3.8 million and $0.4 million, respectively. The federal credits will expire starting in 2044 if not utilized, and the state research credit can be carried forward indefinitely.

The Tax Reform Act of 1986 limits the use of net operating loss carryforwards in certain situations where changes occur in the stock ownership of a company. The annual limitation may result in the expiration of net operating losses and credits before utilization. The Company has not performed a Section 382 analysis through December 31, 2025. To the extent that an assessment is completed in the future, the Company's ability to utilize tax attributes could be restricted on a year-by-year basis and certain attributes could expire before they are utilized. The Company will examine the impact of any potential ownership changes in the future.

A reconciliation of the beginning and ending amount of gross unrecognized tax benefits is as follows (in thousands):

	Year Ended December 31, 2025	Period from February 6, 2024 (inception) to December 31, 2024
Beginning balance	$ 1,047	$ —
Additions based on tax positions taken in the current year	895	1,047
Reductions for tax positions taken in prior years	(123)	—
Ending balance	$ 1,819	$ 1,047

The Company includes penalties and interest expense related to income taxes as a component of income tax expense, as necessary. As of December 31, 2025 and 2024, the Company had no accrued interest or penalties related to uncertain tax positions.

The Company files income tax returns in the United States federal jurisdiction and various state jurisdictions. The Company is not currently under examination by income tax authorities in federal, state, or other jurisdictions.

14. Option Agreements and License Agreements

Option Agreements — Paragon Therapeutics

In March 2024, the Company entered into two antibody discovery and option agreements (the "Option Agreements") with Paragon Therapeutics, Inc. ("Paragon") and Paruka. Under the terms of each agreement, Paragon identifies, evaluates, and develops antibodies directed against certain mutually agreed therapeutic targets of interest to the Company. From time to time, the Company can choose to add additional targets to the collaboration upon agreement with Paragon and Paruka. Under the Option Agreements, 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 rights, titles, 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) (each, an "Option"). The Company has initiated certain research programs with Paragon that generally focus on discovering, generating, identifying and/or characterizing antibodies directed to a particular target (each, a "Research Program"), including for IL-23 and IL-17A/F for ORKA-001 and ORKA-002, respectively. The exclusive option with respect to each Research Program is exercisable at the Company's sole discretion at such time as specified in the Option Agreements (the "Option Period"). There is no payment due upon exercise of an Option pursuant to the Option Agreements.

In December 2025, the Company entered into an additional option agreement for an antibody with Paragon and Paruka to enter into a license agreement, which the Company exercised in December 2025. For the year ended December 31, 2025 the Company incurred $1.5 million related to this additional option agreement which was recognized as research and development expense. Per the terms of this option agreement, once the Company enters into the corresponding license agreement, it will be required to make non-refundable milestone payments to Paragon of up to $12.0 million under the agreement upon the achievement of certain clinical development milestones, up to $10.0 million under the agreement upon the achievement of certain regulatory milestones, as well as a low single-digit percentage royalty for antibody products beginning on the first commercial sale. As of December 31, 2025, the Company has not entered into a license agreement with Paragon and Paruka related to this additional option agreement.

As part of the Option Agreements and the additional option agreement mentioned above, on December 31, 2024, the Company settled its 2024 obligations under the Paruka Warrant Obligation by issuing Paruka a warrant to purchase 596,930 shares of Company Common Stock at an exercise price of $19.39 per share, and on December 12, 2025, the Company settled its 2025 obligations under the Paruka Warrant Obligation by issuing Paruka a warrant to purchase 375,000 shares of Company Common Stock at an exercise price of $30.18 per share.

License Agreements — Paragon Therapeutics

In September 2024, the Company exercised its exclusive option to acquire certain rights to ORKA-001, and in December 2024, it entered into a corresponding license agreement with Paragon (the "ORKA-001 License Agreement"), pursuant to which Paragon granted the Company a royalty-bearing, world-wide, exclusive license to develop, manufacture, commercialize, or otherwise exploit certain antibodies and products targeting IL-23 in all fields other than the field of inflammatory bowel disease ("ORKA-001 Field"). In December 2024, the Company exercised its exclusive option to acquire certain rights to ORKA-002, and in February 2025, it entered into the corresponding license agreement with Paragon (the "ORKA-002 License Agreement" and together with the ORKA-001 License Agreement, the "License Agreements"), pursuant to which Paragon granted the Company a royalty-bearing, world-wide, exclusive license to develop, manufacture, commercialize, or otherwise exploit certain antibodies and products targeting IL-17A/F in all fields ("ORKA-002 Field" and together with the ORKA-001 Field, the "Fields"). Pursuant to each of the two License Agreements, Paragon has agreed not to conduct any new campaigns that generate anti-IL-23 monospecific antibodies or anti-IL-17A/F monospecific antibodies in the respective agreed-upon fields.

The License Agreements provide the Company with exclusive licenses in the Fields to Paragon's patent applications covering the related antibodies, their method of use and their method of manufacture and Paragon has agreed not to conduct any new campaigns that generate anti-IL-23 monospecific antibodies or anti-IL-17A/F monospecific antibodies for the ORKA-001 Field or the ORKA-002 Field, respectively, for at least five years. Each of the License Agreements may be terminated on 60 days' notice to Paragon, on material breach without cure, and on a party's insolvency or bankruptcy to the extent permitted by law.

14. Option Agreements and License Agreements (cont.)

Pursuant to the terms of each of the License Agreements, the Company is obligated to pay Paragon non-refundable milestone payments of up to $12.0 million under each respective agreement upon the achievement of certain clinical development milestones and up to $10.0 million under each respective agreement upon the achievement of certain regulatory milestones. In addition, the Company is obligated to pay Paragon a low single-digit percentage royalty for antibody products for each of ORKA-001 and ORKA-002. For each of the License Agreements, the royalty term ends on the later of (i) the last-to-expire licensed patent or our patent directed to the manufacture, use or sale of a licensed antibody in the country at issue or (ii) 12 years from the date of first sale of a Company product. There is also a royalty step-down if there is no Paragon patent in effect during the royalty term for each program. Each of the License Agreements may be terminated on 60 days' notice to Paragon, on material breach without cure, and on a party's insolvency or bankruptcy to the extent permitted by law. As of December 31, 2025, the Company has incurred and expensed milestone payments of $7.0 million and $4.0 million in connection with the ORKA-001 License Agreement and the ORKA-002 License Agreement, respectively.

Pursuant to the Option Agreements and License 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 certain initiation fees, development costs and milestone payments to Paragon.

For the ORKA-001 program, the Company recognized research and development expenses related to the following milestones during the period from February 6, 2024 (inception) to December 31, 2024: a one-time, nonrefundable research initiation fee of $0.8 million; $1.5 million related to exercising the Company's Option and achievement of development candidate; and $2.5 million related to completing the first dosing of a human subject in a Phase 1 trial. The Company was responsible for 50% of the development costs incurred through the completion of the IL-23 selection process, which was completed in June 2024. An amount of $13.5 million was incurred during the period from February 6, 2024 (inception) to December 31, 2024 for research and development expenses for the ORKA-001 program.

For the ORKA-002 program, the Company recognized research and development expenses related to the following milestones during the period from February 6, 2024 (inception) to December 31, 2024: a one-time, nonrefundable research initiation fee of $0.8 million and $1.5 million related to exercising the Company's Option and achievement of development candidate. The Company was responsible for the development costs incurred through the completion of the IL-23 selection process, which was completed in December 2024. An amount of $11.1 million was incurred during the period from February 6, 2024 (inception) to December 31, 2024 for research and development expenses for the ORKA-002 program.

Pursuant to the Option Agreements and License Agreements, for year ended December 31, 2025, the Company's share of research and development expenses for the ORKA-001 program was nil. The Company recognized a milestone payment of $3.0 million related to completing the first dosing of a human patient in a Phase 2 trial for the ORKA-001 program during the year ended December 31, 2025. These costs were recorded as research and development expenses. As of December 31, 2025 and 2024, nil and $2.8 million, respectively, related to ORKA-001 were included in related party accounts payable and other current liabilities.

Pursuant to the Option Agreements and License Agreements, for the year ended December 31, 2025, the Company's share of research and development expense for the ORKA-002 program was $0.1 million. The Company recognized a milestone payment of $2.5 million related to completing the first dosing of a human subject in a Phase 1 trial for the ORKA-002 program during the year ended December 31, 2025. These costs were recorded as research and development expenses. As of December 31, 2025 and 2024, nil and $2.7 million, respectively, related to ORKA-002 were included in related party accounts payable and other current liabilities.

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 consolidated statements of operations.

14. Option Agreements and License Agreements (cont.)

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.

15. Commitments 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. In February 2025, the Company entered into an operating lease agreement in Waltham, Massachusetts, which commenced on April 1, 2025 with an initial term of 54 months. The Company leases office spaces under noncancelable operating lease agreements. Lease liabilities are based on the net present value of the remaining lease payments over the remaining lease terms. 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.

For the year ended December 31, 2025 and for the period from February 6, 2024 (inception) to December 31, 2024, the Company recorded operating and variable lease expenses of $0.9 million and $0.3 million, respectively, in general and administrative expenses in its consolidated statements of operations.

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

	Year Ended December 31, 2025	Period from February 6, 2024 (inception) to December 31, 2024
Cash paid for amounts included in the measurement of lease liabilities	$ 700	$ 116
Weighted average remaining lease terms (years)	3.0	2.8
Weighted-average discount rate	13.07%	17.95%

The following table summarizes a maturity analysis of the Company's operating lease liabilities showing the aggregate lease payments as of December 31, 2025 (in thousands):

Year ending December 31,	Amount
2026	$ 822
2027	768
2028	397
2029	304
Total undiscounted lease payments	2,291
Less: imputed interest	(359)
Total discounted lease payments	1,932
Less: current portion of lease liability	(619)
Non-current portion of lease liability	$ 1,313

15. Commitments and Contingencies (cont.)

Cell Line License Agreement

In March 2024, the Company entered into the Cell Line License Agreement (the "Cell Line License Agreement") with WuXi Biologics Ireland Limited ("WuXi Biologics"). Under the Cell Line License Agreement, the Company received a non-exclusive, worldwide, sublicensable license to certain of WuXi Biologics' know-how, cell line, biological materials (the "WuXi Biologics Licensed Technology") and media and feeds to make, have made, use, sell and import certain therapeutic products produced through the use of the cell line licensed by WuXi Biologics under the Cell Line License Agreement (the "WuXi Biologics Licensed Products"). Specifically, the WuXi Biologics Licensed Technology is used in certain manufacturing activities in support of the ORKA-001 and ORKA-002 programs.

In consideration for the license, the Company agreed to pay WuXi Biologics a non-refundable license fee of $150,000, which was recognized as a research and development expense during the period from February 6, 2024 (inception) to December 31, 2024. Additionally, to the extent that the Company manufactures its commercial supplies of bulk drug product with a manufacturer other than WuXi Biologics or its affiliates, the Company is required to make royalty payments to WuXi Biologics at a rate of less than one percent of net sales of WuXi Biologics Licensed Products manufactured by the third-party manufacturer. Pursuant to an amendment to the Cell Line License Agreement effective in November 2024, a provision was added that permits the royalties owed under the agreement to be bought out on a product-by-product basis for a lump-sum payment.

The Cell Line License Agreement will continue indefinitely unless terminated (i) by the Company upon six months' prior written notice and its payment of all undisputed amounts due to WuXi Biologics through the effective date of termination, (ii) by WuXi Biologics for a material breach by the Company that remains uncured for 60 days after written notice, (iii) by WuXi Biologics if the Company fails to make a payment and such failure continues for 30 days after receiving notice of such failure, or (iv) by either party upon the other party's bankruptcy.

16. Net Loss Per Share

The following table summarizes the basic and diluted net loss per share attributable to stockholders were calculated as follows (in thousands, except share and per share data):

	Year Ended December 31, 2025			Period from February 6, 2024 (inception) to December 31, 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	$ (84,310)	45,614,142	$ (1.85)	$ (65,037)	16,789,362	$ (3.87)
Company Series A Preferred Stock[1]	—	—	$ —	(1,918)	495	$ (3,873.25)
Company Series B Preferred Stock[2]	(21,123)	137,138	$ (154.03)	(16,769)	51,946	$ (322.81)
Net loss	$ (105,433)			$ (83,724)		

(1) The weighted-average number of shares of as-converted Company Series A Preferred Stock used in the loss allocation was nil and 495,191 for the year ended December 31, 2025 and the period from February 6, 2024 (inception) to December 31, 2024, respectively.

(2) The weighted-average number of shares of as-converted Company Series B Preferred Stock used in the loss allocation was 11,428,129 and 4,328,844 for the year ended December 31, 2025 and the period from February 6, 2024 (inception) to December 31, 2024, respectively.

16. Net Loss Per Share (cont.)

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:

	December 31, 2025	December 31, 2024
Outstanding employee warrants to purchase common stock	3,029,510	3,054,358
Outstanding unvested restricted stock awards	1,149,589	2,207,553
Outstanding and issued common stock options	3,950,958	1,567,760
Outstanding and issued warrant to Paruka	971,930	596,930
Total	9,101,987	7,426,601

17. 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 stock, 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):

	December 31, 2025	December 31, 2024
Paragon reimbursable Option Agreements' fees	$ —	$ 1,482
Paragon milestone payments for License Agreement	—	4,000
Paragon reimbursable other research expenses	—	515
Paragon reimbursable patent expenses	9	25
Total	$ 9	$ 6,022

18. 401(k) Plan

The Company has a retirement and savings plan under Section 401(k) of the Internal Revenue Code (the "401(k) Plan") covering all U.S. employees. The 401(k) Plan allows employees to make pre- and post-tax contributions up to the maximum allowable amount set by the Internal Revenue Service. The Company may make contributions to this plan at its discretion. During the year ended December 31, 2025 the Company matched 100% of each employee's first 3% of pay contributed to the 401(k) Plan. The company match was limited up to $10,500 per employee for the year ended December 31, 2025. The Company recognized an expense of $0.4 million for the year ended December 31, 2025. The Company did not make any matching contributions for the period from February 6, 2024 (inception) to December 31, 2024.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Management's Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Principal Executive Officer and our Principal Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2025. Based on the foregoing evaluation, our Principal Executive Officer and Principal Financial Officer concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of December 31, 2025. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our Principal Executive Officer and Principal Financial Officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP. Our internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management, with the participation of our principal executive officer and principal financial officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2025. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in its 2013 Internal Control — Integrated Framework. Based on our assessment, our management has concluded that, as of December 31, 2025, our internal control over financial reporting was effective based on those criteria.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. For as long as we remain a "smaller reporting company" as defined by Rule 12b-2 of the Exchange Act and report less than $100 million of annual revenues in our most recent fiscal year, we intend to take advantage of the exemption permitting us not to comply with the requirement that our independent registered public accounting firm provide an attestation on the effectiveness of our internal control over financial reporting.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Our management, including our principal executive officer and principal financial officer, believes that our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives and are effective at the reasonable assurance level. However, our management does not expect that our disclosure controls and procedures will prevent or detect all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Item 9B. Other Information.

During the quarter ended December 31, 2025, no director or Section 16 officer (as defined in Section 16 of the Securities Exchange Act of 1934, as amended) 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 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item will be included in our definitive proxy statement for our 2026 annual meeting of stockholders (the "2026 Proxy Statement"), which will be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2025, and is incorporated herein by reference.

Item 11. Executive Compensation.

The information required by this Item is incorporated by reference to the 2026 Proxy Statement.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item is incorporated by reference to the 2026 Proxy Statement.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item is incorporated by reference to the 2026 Proxy Statement.

Item 14. Principal Accountant Fees and Services.

The information required by this Item is incorporated by reference to the 2026 Proxy Statement.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The following documents are filed as part of this Annual Report:

(1) Financial Statements

See Index to Financial Statements included in Part II, Item 8 of this Annual Report.

(2) Financial Statement Schedules

All schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

(3) List of Exhibits required by Item 601 of Regulation S-K

Exhibit Number	Description	Incorporation By Reference		
		Form	Exhibit No.	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	4/3/2024
3.1	Second Amended and Restated Certificate of Incorporation	8-K	3.5	9/5/2024
3.2	Amended and Restated Bylaws	8-K	3.6	9/5/2024
3.3	Form of Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock	S-1/A	3.1(b)	5/24/2013
3.4	Certificate of Elimination of Series A Convertible Preferred Stock, dated August 29, 2024	8-K	3.8	9/5/2024
3.5	Certificate of Designation of Preferences, Rights and Limitations of Series B Non-Voting Convertible Preferred Stock	8-K	3.9	9/5/2024
3.6	Certificate of Designation of Preferences, Rights and Limitations of Series A Non-Voting Convertible Preferred Stock	8-K	3.1	9/13/2024
4.1	Description of Securities	10-K	4.1	3/6/2025
4.2	Form of Pre-Funded Warrant, dated August 29, 2024	10-K	4.3	3/6/2025
4.3	Form of Pre-Funded Warrant, dated September 13, 2024	8-K	4.1	9/13/2024
4.4	Form of Pre-Funded Warrant, dated September 17, 2025	8-K	4.1	9/22/2025
4.5	Paruka Warrant, dated December 31, 2024	10-Q	4.5	5/14/2025
4.6*	Paruka Warrant, dated December 12, 2025			Filed herewith
10.1#	Oruka Therapeutics, Inc. 2024 Stock Incentive Plan	8-K	10.10	9/5/2024
10.2#	Oruka Therapeutics, Inc. 2024 Employee Stock Purchase Plan	8-K	10.11	9/5/2024
10.3#	Amended and Restated 2024 Equity Incentive Plan	S-4	10.40	5/14/2024
10.4#	Second Amendment to the Oruka Therapeutics, Inc. Amended and Restated 2024 Equity Incentive Plan	8-K	10.13	9/5/2024
10.5#	Form of Employee Warrant Agreement	8-K	10.16	9/5/2024
10.6#	Form of Grant Notice for Nonqualified Stock Option and Standard Terms and Conditions for Stock Options (Directors)	S-8	99.2	11/14/2024
10.7#	Form of Grant Notice for Stock Option and Standard Terms and Conditions for Stock Options (Employees)	S-8	99.3	11/14/2024
10.8#	Form of Stock Option Agreement under the Oruka Therapeutics, Inc. Amended and Restated 2024 Equity Incentive Plan	S-4	10.42	5/14/2024
10.9*	Form of Grant Notice for Restricted Stock Unit Award and Standard Terms and Conditions for Restricted Stock Units			Filed herewith
10.10#	Amended and Restated Director Offer Letter, dated March 22, 2024, by and between Oruka Therapeutics, Inc. and Samarth Kulkarni	S-4	10.43	5/14/2024

Exhibit Number	Description	Incorporation By Reference		
		Form	Exhibit No.	Filing Date
10.11#	Director Offer Letter, dated April 24, 2024, by and between Oruka Therapeutics, Inc. and Kristine Ball	S-4	10.44	5/14/2024
10.12#	Director Offer Letter, dated December 1, 2025, by and between Oruka Therapeutics, Inc. and Chris Martin	8-K	10.1	12/11/2025
10.13#	Amended and Restated Employment Letter Agreement by and between Oruka Therapeutics, Inc. and Lawrence Klein, dated October 3, 2024	8-K	10.1	10/4/2024
10.14#	Amended and Restated Employment Letter Agreement by and between Oruka Therapeutics, Inc. and Arjun Agarwal, dated October 3, 2024	8-K	10.2	10/4/2024
10.15#	Amended and Restated Employment Letter Agreement by and between Oruka Therapeutics, Inc. and Paul Quinlan, dated October 1, 2024	10-K	10.17	3/6/2025
10.16#	Amended and Restated Employment Letter Agreement by and between Oruka Therapeutics, Inc. and Joana Goncalves, dated October 1, 2024	10-K	10.18	3/6/2025
10.17#	Amended and Restated Employment Letter Agreement by and between Oruka Therapeutics, Inc. and Laura Sandler, dated July 1, 2025	8-K	10.1	7/1/2025
10.18#	Form of Indemnification Agreement	10-K	10.19	3/6/2025
10.19	Non-Employee Directors Compensation Program	10-K	10.20	3/6/2025
10.20	Form of Amendment to Subscription Agreement	8-K	10.1	7/9/2024
10.21	Form of Amended & Restated Subscription Agreement	8-K	10.2	7/9/2024
10.22	Form of Registration Rights Agreement, dated August 29, 2024	10-Q	10.4	11/13/2024
10.23†	Securities Purchase Agreement by and between Oruka Therapeutics, Inc. and each of the entities listed on Exhibit A thereto, dated September 11, 2024	8-K	10.1	9/13/2024
10.24	Form of Registration Rights Agreement, dated as of September 13, 2024	8-K	10.2	9/13/2024
10.25†	Securities Purchase Agreement by and between Oruka Therapeutics, Inc. and each of the entities listed on Exhibit A thereto, dated September 17, 2025	8-K	10.1	9/22/2025
10.26	Form of Registration Rights Agreement, dated as of September 17, 2025	8-K	10.2	9/22/2025
10.27†	Amended and Restated Antibody Discovery and Option Agreement (IL-17) by and among Paragon Therapeutics, Inc., Paruka Holding, LLC, and Oruka Therapeutics, Inc. dated March 28, 2024	S-4/A	10.50	6/18/2024
10.28†	IL-17 License Agreement by and between Paragon Therapeutics, Inc. and Oruka Therapeutics, Inc., dated February 4, 2025	10-K	10.29	3/6/2025
10.29†	Amended and Restated Antibody Discovery and Option Agreement (IL-23) by and among Paragon Therapeutics, Inc., Paruka Holding, LLC, and Oruka Therapeutics, Inc. dated March 28, 2024	S-4/A	10.51	6/18/2024
10.30†	IL-23 License Agreement by and between Paragon Therapeutics, Inc. and Oruka Therapeutics, Inc., dated December 17, 2024	10-K	10.31	3/6/2025
10.31†	Cell Line License Agreement by and between WuXi Biologics Ireland Limited and Oruka Therapeutics, Inc., dated March 4, 2024	10-K	10.32	3/6/2025
10.32†	Amendment No. 1 to the Cell Line License Agreement by and between WuXi Biologics Ireland Limited and Oruka Therapeutics, Inc., dated November 20, 2024	10-K	10.33	3/6/2025

Exhibit Number	Description	Incorporation By Reference		
		Form	Exhibit No.	Filing Date
10.33	Sales Agreement between Oruka Therapeutics, Inc. and TD Securities (USA) LLC, dated October 3, 2025	S-3	1.2	10/3/2025
14.1	Code of Business Conduct and Ethics	8-K	14.1	9/5/2024
16.1	Letter from KPMG LLP, dated September 5, 2024	8-K	16.1	9/5/2024
19.1	Insider Trading Policy	10-K	19.1	3/6/2025
21.1*	List of subsidiaries of the Registrant			Filed herewith
23.1*	Consent of Independent Registered Public Accounting Firm			Filed herewith
24.1*	Power of Attorney (Incorporated by reference to the signature page of this Annual Report on Form 10-K)			Filed herewith
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			Filed herewith
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			Filed herewith
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			Furnished herewith
97.1*	Incentive Compensation Clawback Policy	10-K	97.1	3/6/2025
101.INS*	Inline XBRL Instance Document			Filed herewith
101.SCH*	Inline XBRL Taxonomy Extension Schema with Embedded Linkbases Document			Filed herewith
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.			Filed herewith
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.			Filed herewith
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document.			Filed herewith
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.			Filed herewith
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.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

Oruka Therapeutics, Inc.

Date: March 12, 2026

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

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Dr. Lawrence Klein and Mr. Arjun Agarwal, jointly and severally, his or her attorneys-in-fact, each with the power of substitution, for him or her in any and all capacities, to sign any amendments to this Report on Form 10-K and to file same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Lawrence Klein Lawrence Klein	Chief Executive Officer & Director (Principal Executive Officer)	March 12, 2026
/s/ Arjun Agarwal Arjun Agarwal	Senior Vice President, Finance and Treasurer (Principal Financial Officer and Principal Accounting Officer)	March 12, 2026
/s/ Samarth Kulkarni Samarth Kulkarni	Chairman of the Board	March 12, 2026
/s/ Kristine Ball Kristine Ball	Director	March 12, 2026
/s/ Carl Dambkowski Carl Dambkowski	Director	March 12, 2026
/s/ Peter Harwin Peter Harwin	Director	March 12, 2026
/s/ Christopher Martin Christopher Martin	Director	March 12, 2026

855 Oak Grove Avenue, Suite 100, Menlo Park, CA 94025

NOTICE OF ANNUAL MEETING OF STOCKHOLDERS
To Be Held on June 2, 2026

Dear Stockholder:

You are cordially invited to attend the Annual Meeting of Stockholders of Oruka Therapeutics, Inc., a Delaware corporation. The meeting will be held virtually on Tuesday, June 2, 2026 at 8:00 a.m. Pacific Time via live audio-only webcast at *www.virtualshareholdermeeting.com/ORKA2026*. The meeting will be held online only. You will be able to vote your shares electronically over the Internet and submit questions online during the meeting by logging in to the website listed above using the 16-digit control number included in your Notice of Internet Availability of Proxy Materials, on your proxy card or on the instructions that accompanied your proxy materials. Online check-in will begin at 7:45 a.m. Pacific Time and you should allow ample time for the check-in procedures. You may submit questions before the meeting by visiting *www.proxyvote.com*.

The Annual Meeting of Stockholders is being convened for the following purposes, as more fully described in the accompanying proxy statement (the "Proxy Statement"):

1. To elect the two Class II director nominees named in the Proxy Statement to serve until the 2029 Annual Meeting of Stockholders and until their successors are duly elected and qualified.
2. To ratify the appointment of PricewaterhouseCoopers LLP as the independent registered public accounting firm of Oruka Therapeutics, Inc. for its fiscal year ending December 31, 2026.
3. To approve, on a non-binding, advisory basis, the compensation for our named executive officers.
4. To conduct any other business properly brought before the meeting or any adjournments or postponements thereof.

These items of business are more fully described in the Proxy Statement accompanying this Notice.

The record date for the Annual Meeting of Stockholders is April 7, 2026. Only stockholders of record at the close of business on that date will be entitled to notice of the meeting and to vote at the meeting.

Unless otherwise announced differently at the meeting or on the meeting website, in the event of a technical malfunction or other situation that the meeting chair determines may affect the ability of the Annual Meeting of Stockholders to satisfy the requirements for a meeting of stockholders to be held by means of remote communication under the Delaware General Corporation Law, or that otherwise makes it advisable to adjourn the Annual Meeting of Stockholders, the meeting chair or secretary will convene the meeting at 9:00 a.m. Pacific Time on the date specified above and at our address specified above solely for the purpose of adjourning the meeting to reconvene at a date, time and physical or virtual location announced by the meeting chair or secretary. Under either of the foregoing circumstances, we will post information regarding the announcement on the Investors page of our website at orukatx.com.

Important Notice Regarding the Availability of Proxy Materials for the Annual Meeting of Stockholders to be held virtually on June 2, 2026 via live audio-only webcast at *www.virtualshareholdermeeting.com/ORKA2026*

The Proxy Statement and Annual Report to Stockholders are available at *www.proxyvote.com*.

OUR BOARD RECOMMENDS A VOTE "FOR" THE ELECTION OF THE TWO DIRECTOR NOMINEES NAMED IN THIS PROXY STATEMENT, AND "FOR" PROPOSALS 2 AND 3.

By Order of the Board of Directors

/s/ Paul Quinlan
Paul Quinlan
Corporate Secretary

Menlo Park, California
April 17, 2026

You are cordially invited to attend the meeting virtually. Whether or not you expect to attend the meeting virtually via live webcast, please complete, date, sign and return the proxy card or voting instruction form if sent to you, or vote over the telephone or the Internet as instructed in these materials, as promptly as possible in order to ensure your representation at the meeting. Even if you have voted by proxy, you may still vote electronically during the meeting.

855 Oak Grove Avenue, Suite 100, Menlo Park, CA 94025

PROXY STATEMENT

The following information is a summary only and does not contain all the information that you should consider in connection with this Proxy Statement. Please read the entire Proxy Statement carefully before voting.

Annual Meeting of Stockholders

- Date and Time: Tuesday, June 2, 2026 at 8:00 a.m. Pacific Time. Online check-in will begin at 7:45 a.m. Pacific Time and you should allow ample time for the check-in procedures.
- Location: The meeting will be held virtually via live audio-only webcast at *www.virtualshareholdermeeting.com/ORKA2026*.
- Admission: To attend the meeting, you will need the 16-digit control number included in your Notice of Internet Availability of Proxy Materials, on your proxy card or on the instructions that accompanied your proxy materials.
- Record Date: April 7, 2026.
- Proxy Mailing Date: Beginning on or about April 17, 2026.
- Stockholders as of the Record Date are entitled to notice of the Annual Meeting and to vote. Each share of common stock is entitled to one vote for each director nominee and one vote for each of the proposals.

Voting Matters

Stockholders are being asked to vote on the following matters:

PROPOSALS	VOTING STANDARD	BOARD VOTE RECOMMENDATION
1. Election of Directors	Plurality	**FOR ALL** of the two nominees
2. Ratification of the appointment of the independent registered public accounting firm	Majority of the shares present in person or represented by proxy and entitled to vote on the matter	**FOR**
3. Non-binding advisory approval of the compensation of our named executive officers as disclosed in this Proxy Statement	Majority of the shares present in person or represented by proxy and entitled to vote on the matter	**FOR**

The Proxy Statement and Annual Report to Stockholders are available at *www.proxyvote.com*.

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LEGAL MATTERS

Acquisition of Pre-Merger Oruka. On August 29, 2024 (the "Merger Closing"), we completed our acquisition (the "Merger") of Oruka Therapeutics, Inc. ("Pre-Merger Oruka") pursuant to an Agreement and Plan of Merger and Reorganization, dated as of April 3, 2024 (the "Merger Agreement"). Following the transactions contemplated by the Merger Agreement, Pre-Merger Oruka merged with and into Atlas Merger Sub Corp., a wholly owned subsidiary of ARCA biopharma, Inc. ("ARCA") and following that, Pre-Merger Oruka then merged with and into Atlas Merger Sub II, LLC ("Second Merger Sub"), with Second Merger Sub being the surviving entity. Second Merger Sub changed its corporate name to "Oruka Therapeutics Operating Company, LLC." Pre-Merger Oruka was a pre-clinical stage biotechnology company that was incorporated on February 6, 2024. On August 29, 2024, we changed our name from "ARCA biopharma, Inc." to "Oruka Therapeutics, Inc." and our Nasdaq ticker symbol from "ABIO" to "ORKA".

Important Notice Regarding the Availability of Proxy Materials for the 2026 Annual Meeting of Stockholders to Be Held on June 2, 2026. The Proxy Statement and Annual Report for the year ended December 31, 2025 are available at *www.proxyvote.com*.

Forward-Looking Statements. The Proxy Statement may contain "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, which statements are subject to substantial risks and uncertainties and are based on estimates and assumptions. All statements other than statements of historical fact included in the Proxy Statement, including statements about the Company's Board of Directors, corporate governance practices and executive compensation program and equity compensation utilization, are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "design," "estimate," "predict," "potential," "plan" or the negative of these terms, and similar expressions intended to identify forward-looking statements.

These statements involve known and unknown risks, uncertainties and other factors that could cause our actual results or outcomes to differ materially from the forward-looking statements expressed or implied in the Proxy Statement. Such risks, uncertainties and other factors include those risks described in "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in the Company's most recent Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission ("SEC") and other subsequent documents we file with the SEC. The Company expressly disclaims any obligation to update or alter any statements whether as a result of new information, future events or otherwise, except as required by law.

Website References. Website references throughout this document are inactive textual references and provided for convenience only, and the content on the referenced websites is not incorporated herein by reference and does not constitute a part of the Proxy Statement.

Use of Trademarks. Oruka Therapeutics and the Oruka logo are trademarks of Oruka Therapeutics, Inc. Other names and brands may be claimed as the property of others.

855 Oak Grove Avenue, Suite 100, Menlo Park, CA 94025

PROXY STATEMENT
FOR THE 2026 ANNUAL MEETING OF STOCKHOLDERS

QUESTIONS AND ANSWERS ABOUT THE PROXY MATERIALS AND VOTING

What is the purpose of these proxy materials?

We are making these proxy materials available to you in connection with the solicitation of proxies by the Board of Directors (the "Board") of Oruka Therapeutics, Inc. ("we," "us," "our," "Oruka" or the "Company") for use at the 2026 Annual Meeting of Stockholders (the "Annual Meeting") to be held virtually on June 2, 2026 at 8:00 a.m. Pacific Time, or at any other time following adjournment or postponement thereof. You are invited to participate in the Annual Meeting and to vote on the proposals described in this proxy statement (the "Proxy Statement").

Why did I receive a notice regarding the availability of proxy materials on the Internet?

We have elected to provide access to our proxy materials over the Internet and have provided our stockholders with instructions on how to access the proxy materials in the Notice of Internet Availability of Proxy Materials (the "Notice") that you received.

Rules adopted by the Securities and Exchange Commission ("SEC") allow us to provide access to our proxy materials over the Internet. Stockholders will have the ability to access the proxy materials on the website at *www.proxyvote.com*, or may request a printed set of the proxy materials. Instructions on how to access the proxy materials or to request a printed copy may be found in the Notice.

We intend to mail the Notice to all stockholders of record entitled to vote at the Annual Meeting beginning on or about April 17, 2026.

Why are we holding a virtual Annual Meeting?

We have adopted a virtual meeting format for the Annual Meeting to provide a consistent experience to all stockholders regardless of geographic location. We believe this expands stockholder access, improves communications and lowers our costs while reducing the environmental impact of the meeting. In structuring our virtual Annual Meeting, our goal is to enhance rather than constrain stockholder participation in the meeting, and we have designed the meeting to provide stockholders with the same rights and opportunities to participate as they would have at an in-person meeting.

Additional information may be found at *www.orukatx.com*. Information on how to vote over the Internet before and during the Annual Meeting is discussed below.

How do I attend the Annual Meeting?

The Annual Meeting will be held virtually on June 2, 2026 at 8:00 a.m. Pacific Time via live audio-only webcast at *www.virtualshareholdermeeting.com/ORKA2026*. Stockholders of record as of the close of business on the Record Date (as defined below) are entitled to attend the Annual Meeting. To attend the meeting, stockholders of record will need the 16-digit control number included in your Notice, on your proxy card or on the instructions that accompanied your proxy materials. If your shares are held in "street name" and your voting instruction form indicates that you may vote those shares through *www.proxyvote.com*, then you may attend the Annual Meeting with the 16-digit access code indicated on that voting instruction form. Otherwise, stockholders who hold their shares

in street name should contact their broker, bank or other nominee (preferably at least five days before the Annual Meeting) and obtain a "legal proxy" to be able to attend or vote at the Annual Meeting. Online check-in will begin at 7:45 a.m. Pacific Time and you should allow ample time for the check-in procedures.

Additional information regarding the rules and procedures for participating in the Annual Meeting will be set forth in our meeting rules of conduct, which stockholders can view during the meeting at the meeting website.

How do I ask questions at the virtual Annual Meeting?

You may submit questions before the meeting by visiting *www.proxyvote.com*. During the Annual Meeting, you may only submit questions in the question box provided at *www.virtualshareholdermeeting.com/ORKA2026*. We will endeavor to respond to as many stockholder-submitted inquiries at the Annual Meeting as time allows that comply with the Annual Meeting rules of conduct. We reserve the right to edit profanity or other inappropriate language and to exclude questions regarding topics that are not pertinent to meeting matters or Company business. If we receive substantially similar questions, we may group such questions together and provide a single response to avoid repetition.

What if during the check-in time or during the Annual Meeting I have technical difficulties or trouble accessing the virtual meeting website?

We will have technicians ready to assist you with any technical difficulties you may have accessing the virtual meeting website. If you encounter any difficulties accessing the virtual Annual Meeting during the check-in or meeting time, please call the technical support number that will be posted on the Annual Meeting website log-in page.

What if I cannot attend the Annual Meeting online?

You may vote your shares by proxy electronically before the meeting over the Internet or by telephone, or may vote your shares by proxy by sending a proxy card, as described below. You do not need to access the Annual Meeting to vote if you submitted your vote via proxy card, over the Internet or by telephone in advance of the Annual Meeting.

Who can vote at the Annual Meeting?

Only stockholders at the close of business on April 7, 2026 (the "Record Date"), will be entitled to vote at the Annual Meeting. On the Record Date, there were 50,196,914 shares of our common stock issued and outstanding and entitled to vote. Shares of our preferred stock generally do not have voting rights and holders of our preferred stock are therefore not entitled to vote at the Annual Meeting.

Stockholders of Record: Shares Registered in Your Name

If on April 7, 2026, your shares were registered directly in your name with Oruka's transfer agent, Computershare Trust Company N.A., then you are a stockholder of record. As a stockholder of record, you may vote in person at the meeting or vote by proxy. Whether or not you plan to attend the meeting, we urge you to fill out and return a proxy card, or vote by proxy over the telephone or over the Internet as instructed in the Notice, the proxy card or below, to ensure your vote is counted.

Beneficial Owner: Shares Registered in the Name of a Broker, Bank or Other Nominee

If at the close of business on April 7, 2026, your shares were held, not in your name, but rather in an account at a brokerage firm, bank or other nominee, then you are the beneficial owner of shares held in "street name" and these proxy materials are being forwarded to you by that organization. The organization holding your account is the stockholder of record for purposes of voting at the Annual Meeting. As a beneficial owner, you have the right to direct your broker, bank or other nominee regarding how to vote the shares in your account. You are also invited to attend the Annual Meeting. If your voting instruction form indicates that you may vote your shares through *www.proxyvote.com*, then you may attend the meeting and vote your shares over the Internet during the meeting with

the 16-digit control number included in the voting instruction form provided by your broker, bank or other agent. If you do not have a 16-digit control number and wish to vote at the meeting, please contact your broker, bank or other nominee for instructions on how to vote.

What am I voting on?

There are three matters scheduled for a vote:

- Election of two Class II director nominees named in the Proxy Statement to serve until the 2029 Annual Meeting of Stockholders and until their successors are duly elected and qualified ("Proposal 1");
- Ratification of the appointment of PricewaterhouseCoopers LLP as the independent registered public accounting firm of Oruka for its fiscal year ending December 31, 2026 ("Proposal 2"); and
- Non-binding advisory vote to approve the compensation of our named executive officers as disclosed in this Proxy Statement ("Proposal 3").

What if another matter is properly brought before the meeting?

As of the date of filing this Proxy Statement, the Board knows of no other matters that will be presented for consideration at the Annual Meeting. If any other matters are properly brought before the meeting, it is the intention of the persons named as proxies in the accompanying proxy card to vote, to the extent permitted by SEC rules, on those matters in accordance with their best judgment.

What are the voting recommendations of the Board?

The Board recommends that you vote your shares "**FOR ALL**" of the two nominees in Proposal 1 and "**FOR**" Proposals 2 and 3.

How do I vote?

Even if you plan to attend the Annual Meeting, we recommend that you also submit your vote as early as possible in advance so that your vote will be counted if you later decide not to, or are unable to, attend the Annual Meeting online.

Stockholder of Record: Shares Registered in Your Name

If you are a stockholder of record, you may vote over the Internet before or during the Annual Meeting, by telephone or by proxy. Whether or not you plan to attend the meeting, we urge you to vote as early as possible to ensure your vote is counted.

- If you requested paper copies of the proxy materials, to vote using the proxy card, simply complete, sign, date and return the proxy card pursuant to the instructions on the card. If you return your signed proxy card to us before the Annual Meeting, we will vote your shares as you direct us to.
- If you requested paper copies of the proxy materials, to vote by telephone, dial toll-free 1-800-690-6903 using a touch-tone phone and follow the recorded instructions. You will be asked to provide the company number and control number from the Notice or proxy card. Your telephone vote must be received by 11:59 p.m., Eastern Time on June 1, 2026, to be counted.
- To vote over the Internet before the meeting, go to *www.proxyvote.com* to complete an electronic proxy card. You will be asked to provide the company number and control number from the Notice or proxy card. Your internet vote must be received by 11:59 p.m., Eastern Time on June 1, 2026, to be counted.
- To vote over the Internet during the meeting, please visit *www.virtualshareholdermeeting.com/ORKA2026* and have available the 16-digit control number included in your Notice, on your proxy card or on the instructions that accompanied your proxy materials.

Beneficial Owner: Shares Registered in the Name of Broker, Bank or Other Nominee

If you are a beneficial owner of shares registered in the name of your broker, bank or other nominee, you should have received a voting instruction form from that organization rather than from Oruka. Simply follow the voting instructions in the voting instruction form to ensure that your vote is counted. If your voting instruction form indicates that you may vote your shares through *www.proxyvote.com*, you may vote your shares over the Internet during the meeting with the 16-digit control number indicated on the voting instruction. If you do not have a 16-digit control number and wish to vote at the meeting please contact your broker, bank, or other nominee for instructions on how to vote.

How many votes do I have?

Each share of common stock is entitled to one vote for each director nominee and one vote for each of the proposals.

What happens if I do not vote?

Stockholder of Record: Shares Registered in Your Name

If you are a stockholder of record and do not vote in one of the ways described above, your shares will not be voted at the Annual Meeting and will not be counted toward the quorum requirement.

Beneficial Owner: Shares Registered in the Name of Broker, Bank or Other Nominee

If you are a beneficial owner and do not direct your broker, bank or other nominee how to vote your shares, your broker, bank or other nominee will only be able to vote your shares with respect to proposals considered to be "routine." Your broker, bank or other nominee is not entitled to vote your shares with respect to "non-routine" proposals, which we refer to as a "broker non-vote." Whether a proposal is considered routine or non-routine is subject to stock exchange rules and final determination by the stock exchange. Even with respect to routine matters, some brokers choose not to exercise discretionary voting authority. As a result, we urge you to direct your broker, bank or other nominee how to vote your shares on all proposals to ensure that your vote is counted.

What if I sign and return a proxy card or otherwise vote but do not make specific choices?

Stockholder of Record: Shares Registered in Your Name

The shares represented by each signed and returned proxy will be voted at the Annual Meeting by the persons named as proxies in the proxy card in accordance with the instructions indicated on the proxy card. However, if you are the stockholder of record and sign and return your proxy card without giving specific instructions, the persons named as proxies in the proxy card will vote your shares in accordance with the recommendations of the Board. Your shares will be counted toward the quorum requirement.

Beneficial Owner: Shares Registered in the Name of Broker, Bank or Other Nominee

If you are the beneficial owner and do not direct your broker, bank or other nominee how to vote your shares, your broker, bank or other nominee will only be able to vote your shares with respect to proposals considered to be "routine," as described above under "What happens if I do not vote."

Who is paying for this proxy solicitation?

We will pay for the cost associated with the solicitation of proxies, including the preparation, assembly, printing and mailing of the proxy materials. In addition to these proxy materials, our directors and employees may also solicit proxies in person, by telephone, or by other means of communication. Directors and employees will not be paid any additional compensation for soliciting proxies. We may also reimburse broker, bank or other nominee for the cost of forwarding proxy materials to beneficial owners of shares of common stock held in "street name."

What does it mean if I receive more than one Notice or proxy card?

If you receive more than one Notice or proxy card, your shares may be registered in more than one name or in different accounts. Please cast your vote with respect to each Notice or proxy card that you receive to ensure that all your shares are voted.

Can I change my vote after submitting my proxy?

Yes. You can revoke your proxy at any time before the final vote at the meeting.

Stockholder of Record: Shares Registered in Your Name

If you are the stockholder of record, you may revoke your proxy in any one of the following ways:

- You may submit another properly completed proxy card with a later date.
- You may grant a subsequent proxy by telephone or over the Internet.
- You may send a timely written notice that you are revoking your proxy to Oruka's Corporate Secretary at 855 Oak Grove Avenue, Suite 100, Menlo Park, CA 94025.
- You may attend the Annual Meeting online and vote over the Internet by visiting *www.virtualshareholdermeeting.com/ORKA2026*, using the 16-digit control number described above under "How do I attend the Annual Meeting."

Your last submitted vote is the one that is counted.

Beneficial Owner: Shares Registered in the Name of Broker, Bank or Other Nominee

If your shares are held by your broker, bank or other nominee, you should follow the instructions provided by your broker, bank or nominee.

What is the quorum requirement?

A quorum of stockholders is necessary to hold a valid meeting. A quorum will be present if stockholders holding at least a majority of the outstanding shares of common stock entitled to vote at the meeting are present virtually or represented by proxy. On the Record Date, there were 50,196,914 shares outstanding and entitled to vote. Thus, the holders of 25,098,458 shares must be present in person or represented by proxy at the meeting to have a quorum.

Your shares will be counted toward the quorum only if you submit a valid proxy (or one is submitted on your behalf by your broker, bank or other nominee) or if you virtually attend the Annual Meeting and vote over the Internet during the Annual Meeting by visiting *www.virtualshareholdermeeting.com/ORKA2026*. Abstentions and broker non-votes, if any, will be counted toward the quorum requirement. If there is no quorum, the chair of the meeting or the holders of a majority of shares of common stock present at the meeting, virtually or represented by proxy, may adjourn the meeting to another time or date.

How are votes counted?

Votes will be counted by the inspector of election appointed for the meeting, who will separately count (a) for Proposal 1, votes "FOR ALL" nominees, "WITHHOLD ALL" nominees, "FOR ALL Except" for any nominee you specify and broker non-votes, if any, (b) with respect to Proposal 2, votes "FOR," "AGAINST," and abstentions and (c) with respect to Proposal 3, votes "FOR," "AGAINST," abstentions and broker non-votes, if any.

How many votes are needed to approve each proposal?

- *Proposal 1: Election of Directors*

  A nominee will be elected as a director at the Annual Meeting if the nominee receives a plurality of the votes cast "FOR" their election. "Plurality" means that the individuals who receive the highest number of votes cast "FOR" will be elected as directors. Only votes "FOR" will affect the outcome. Votes "WITHHELD" and broker non-votes, if any, will not be counted as votes cast on the matter and will have no effect other than for purposes of determining a quorum, as described above. Stockholders do not have cumulative voting rights for the election of directors.

- *Proposal 2: Ratification of Independent Auditor Appointment*

  The affirmative vote of the holders of at least a majority of shares of common stock present or represented at the Annual Meeting and entitled to vote on the matter is required to approve this proposal. Abstentions will have the same effect as a vote "AGAINST" the matter. Proposal 2 is considered a routine matter and accordingly, if you do not instruct your broker or other nominee on how to vote the shares in your account on such proposal, brokers will be permitted to exercise their discretionary authority to vote on this proposal.

- *Proposal 3: Non-Binding Advisory Vote to Approve Named Executive Officer Compensation*

  The affirmative vote of the holders of at least a majority of shares of common stock present or represented at the Annual Meeting and entitled to vote on the matter is required to approve this proposal. Abstentions will have the same effect as a vote "AGAINST" the matter. Broker non-votes, if any, will have no effect on the outcome of the matter.

Your vote on Proposal 3 is advisory, which means that the results are non-binding on us, our Board and its committees. Although non-binding, our Board and its committees value the opinions of our stockholders and will review and consider the voting results when making future decisions regarding the compensation of our named executive officers.

How can I find out the results of the voting at the Annual Meeting?

Preliminary voting results are expected to be announced at the Annual Meeting. In addition, final voting results will be published in a Current Report on Form 8-K that we expect to file within four business days after the Annual Meeting. If final voting results are not available to us in time to file a Form 8-K within four business days after the meeting, we intend to file a Form 8-K to publish preliminary results and, within four business days after the final results are known to us, file an additional Form 8-K to publish the final results.

What proxy materials are available on the Internet?

The Notice and Proxy Statement and Annual Report to Stockholders are available at *www.proxyvote.com*.

PROPOSAL 1

ELECTION OF DIRECTORS

In accordance with our Certificate of Incorporation and Bylaws, the Board has fixed the number of directors constituting the Board at six. At the Annual Meeting, the stockholders will vote to elect the two Class II director nominees named in this Proxy Statement to serve until the 2029 Annual Meeting of Stockholders or until their successors are duly elected and qualified and until their earlier resignation or removal. Our Board has nominated Lawrence Klein and Chris Martin for election to our Board. Dr. Klein was appointed to the Board in August 2024 in accordance with the Merger Agreement while Mr. Martin was appointed to the Board in December 2025.

Our director nominees have indicated that they are willing and able to serve as directors. However, if either of them becomes unable or, for good cause, unwilling to serve, proxies may be voted for the election of such other person as shall be designated by our Board, or the Board may decrease the size of the Board.

Information Regarding Director Nominees and Continuing Directors

Our Board is divided into three classes, with members of each class holding office for staggered three-year terms. There are currently two Class II directors, who are up for election at this meeting for a term expiring at the 2029 Annual Meeting of Stockholders; two Class III directors, whose terms expire at the 2027 Annual Meeting of Stockholders; and two Class I directors, whose terms expire at the 2028 Annual Meeting of Stockholders.

Biographical and other information regarding our director nominees and directors continuing in office, including the primary skills and experiences considered by our Nominating and Corporate Governance Committee (the "Nominating Committee") in determining to recommend them as nominees, is set forth below:

NAME	CLASS	AGE*	POSITION HELD WITH ORUKA
Carl Dambkowski[(1)]	I	41	Director
Peter Harwin[(2)(3)]	I	40	Director
Lawrence Klein	II	43	Chief Executive Officer and Director
Chris Martin[(1)(2)]	II	50	Director
Kristine Ball[(1)(3)]	III	54	Director
Samarth Kulkarni[(2)(3)]	III	47	Director and Chair

(1) Member of the Audit Committee.
(2) Member of the Compensation Committee.
(3) Member of the Nominating Committee.
* As of April 17, 2026

Class II Director Nominees

Lawrence Klein, Ph.D. Dr. Klein has served as President and Chief Executive Officer and as a member of the board of directors of the Company since the Merger Closing and of Pre-Merger Oruka from February 2024 through the Merger Closing. Prior to joining Pre-Merger Oruka, Dr. Klein was a Partner at Versant Venture Management, LLC, a healthcare and biotechnology venture capital firm, from January 2023 to February 2024, where he invested in and helped to grow early-stage biotechnology companies. Prior to Versant, Dr. Klein served in various positions at CRISPR Therapeutics AG (Nasdaq: CRSP), a biopharmaceutical company, including Chief Operating Officer from January 2020 to October 2022, Chief Business Officer from January 2019 to January 2020, Senior Vice President, Business Development and Strategy from November 2017 to December 2018 and as Vice President, Strategy from February 2016 to November 2017, where he helped to initiate and execute on several transformative partnerships, establish the strategic direction of the company, oversee important pipeline programs and led several functions, including program and portfolio management. Before joining CRISPR, Dr. Klein was an Associate Partner at McKinsey & Company, a global management consulting firm, from October 2014 to February 2016. Dr. Klein served as a member of the board of directors of Dyne Therapeutics, Inc. (Nasdaq: DYN) from September 2019 to May 2023 and of Jasper Therapeutics, Inc. (Nasdaq: JSPR) from September 2021 to June 2023. Dr. Klein received his B.S. in biochemistry and physics from the University of Wisconsin-Madison and his Ph.D. in biophysics from Stanford University.

We believe Dr. Klein is qualified to serve as a member of the Board because of his business development, operational and senior management experience in the biotechnology industry and his academic expertise and accomplishments.

Chris Martin. Mr. Martin has served as a member of the board of directors of the Company since December 2025. Mr. Martin, age 50, served as Chief Commercial Officer from January 2024 to October 2025 for Verona Pharma, a biopharmaceutical company, which was acquired by Merck & Co. in October 2025. As Chief Commercial Officer, Mr. Martin was responsible for building the commercial organization and launch strategy for the company's first product launch. Mr. Martin previously served in other management positions at Verona, including Senior Vice President of Commercial from January 2022 to December 2023 and Vice President of Commercial from June 2020 and December 2022. Prior to Verona, he served as Executive Director of Marketing at SK Life Science, which is focused on developing novel therapeutics for central nervous system conditions, from March 2018 to June 2020. Mr. Martin was instrumental in developing the commercial and marketing strategy and the framework for launching their first commercial product. Until its acquisition by Melinta Therapeutics, Mr. Martin was Head of Marketing at Cempra where he led the development and launch strategy for the company's first product. Prior to Cempra, he was at Salix Pharmaceuticals for 10 years in roles of increasing responsibility. Mr. Martin also is a member of the board of directors of Edgewise Therapeutics, Inc. (Nasdaq: EWTX). Mr. Martin received a Bachelor of Science in Financial Management from Clemson University.

We believe Mr. Martin is qualified to serve as a member of the Board because of his experience as a leader in building commercial organizations and commercializing biopharmaceutical products.

Class III Directors Continuing in Office

Kristine Ball. Ms. Ball has served as a member of the board of directors of the Company since the Merger Closing and of Pre-Merger Oruka since May 2024 through the Merger Closing. Ms. Ball has served as President and Chief Executive Officer of Antiva Biosciences, Inc., a private biopharmaceutical company, since April 2023. Prior to Antiva, Ms. Ball served as Chief Executive Officer of Soteria Biotherapeutics, Inc., a private biotechnology company, from September 2020 to August 2022. Prior to joining Soteria, Ms. Ball served as Senior Vice President, Corporate Strategy and Chief Financial Officer of Menlo Therapeutics, Inc., a Nasdaq-listed biopharmaceutical company, which later became VYNE Therapeutics Inc. (Nasdaq: VYNE), from September 2017 to March 2020, where she was responsible for leading all non-R&D functions, including strategic planning, corporate development, commercial, human resources, legal, finance and information technology. Prior to joining Menlo, Ms. Ball served as Chief Financial Officer and Senior Vice President of Relypsa, Inc., a Nasdaq-listed pharmaceutical company, which was later acquired by Galenica Group, from November 2012 to October 2016. Prior to Relypsa, Ms. Ball held various other finance roles in the life sciences industry, including Senior Vice President of Finance & Administration and Chief Financial Officer of KAI Pharmaceuticals, Inc., a biopharmaceutical company, and Vice President of Finance at Exelixis, Inc. (Nasdaq: EXEL), a biotechnology company. Prior to that, Ms. Ball served as a senior manager in the life sciences audit practice of Ernst & Young LLP. Ms. Ball has previously served on the boards of directors of Atreca, Inc. (Nasdaq: BCEL), a biopharmaceutical company, from 2020 to 2024, Soteria from 2020 to 2022 and Forty Seven, Inc. (Nasdaq: FTSV), a Nasdaq-listed biotechnology company, which was acquired by Gilead Sciences, Inc., from 2018 to 2020. Ms. Ball received a B.S. from Babson College.

We believe Ms. Ball is qualified to serve as a member of the Board because of her experience as an executive officer and director of life sciences companies and her background in finance, corporate development and strategic planning.

Samarth Kulkarni, Ph.D. Dr. Kulkarni has served as Chair and a member of the board of directors of the Company since the Merger Closing and as a member of the board of directors of Pre-Merger Oruka from February 2024 through the Merger Closing. Dr. Kulkarni has served as the Chief Executive Officer of CRISPR Therapeutics AG (Nasdaq: CRSP), a biopharmaceutical company, since December 2017, where he has also served as a member and chair of the board of directors since June 2018 and September 2023, respectively. Previously, Dr. Kulkarni served as CRISPR's President and Chief Business Officer from May 2017 to November 2017 and as Chief Business Officer from August 2015. Prior to joining CRISPR, Dr. Kulkarni was at McKinsey & Company, a global management consulting firm, from 2006 to 2015, with various titles, his most recent being Partner within the

Pharmaceuticals and Biotechnology practice. Dr. Kulkarni has also served as a member of the boards of directors of Black Diamond Therapeutics, Inc. (Nasdaq: BDTX), Repare Therapeutics Inc. (Nasdaq: RPTX), and Centessa Pharmaceuticals plc (Nasdaq: CNTA). Dr. Kulkarni received a Ph.D. in Bioengineering and Nanotechnology from the University of Washington and a B. Tech. from the Indian Institute of Technology. Dr. Kulkarni has authored several publications in leading scientific and business journals.

We believe that Dr. Kulkarni is qualified to serve as a member of the Board because of his experience as a consultant and an executive in the biopharmaceutical industry and his academic expertise and accomplishments.

Class I Directors Continuing in Office

Carl Dambkowski, M.D. Dr. Dambkowski has served as a member of the board of directors of the Company since the Merger Closing and of Pre-Merger Oruka from February 2024 through the Merger Closing. Dr. Dambkowski has served as the Chief Medical Officer of Apogee Therapeutics, Inc. (Nasdaq: APGE), a biotechnology company, since September 2022. Prior to joining Apogee, Dr. Dambkowski served as a strategic and clinical leader for a variety of companies, including as Chief Medical Officer of QED Therapeutics, Inc., a private biotechnology company, from July 2021 to September 2022; Chief Strategy Officer and EVP of Operations of Origin Biosciences, Inc., a private bioecology company, from March 2018 to June 2021; and Chief Medical Officer of Navire Pharma, Inc., a private biotechnology company, from January 2020 to September 2022, where he served as the clinical lead starting prior to IND for BBP-398 through the out licensing of the compound to Bristol-Myers Squibb based on initial clinical data and for low-dose infigratinib in achondroplasia through initial proof-of-concept data. He was part of the core team that brought TRUSELTIQ® (infigratinib) and NULIBRY® (fosdenopterin) through regulatory review and FDA approval at QED Therapeutics and Origin Biosciences, respectively. From July 2016 to March 2018, Dr. Dambkowski was an associate at McKinsey & Company, a global management consulting firm, where he advised biotech and pharmaceutical companies across the world on a range of research and development activities. Dr. Dambkowski co-founded Novonate, Inc., a private medical device company focused on building life-saving devices for neonates, in January 2015. Dr. Dambkowski has coauthored numerous peer-reviewed publications and scientific abstracts and is a named inventor on multiple published and granted patents. Dr. Dambkowski was trained as a physician at Stanford University, where he also received his M.D. with a concentration in bioengineering. He also received a B.A. (with honors) from Stanford University and an M.A. from Columbia University.

We believe Dr. Dambkowski is qualified to serve as a member of the Board because of his significant experience and innovations in the biotechnology industry and his academic expertise and accomplishments.

Peter Harwin. Mr. Harwin has served as a member of the board of directors of the Company since the Merger Closing and of Pre-Merger Oruka from February 2024 through the Merger Closing. Mr. Harwin is a Founding Partner at Fairmount Funds Management LLC, a healthcare investment firm he co-founded in April 2016. Prior to Fairmount Funds Management, Mr. Harwin was a member of the investment team at Boxer Capital, LLC, an investment fund that was part of the Tavistock Group, based in San Diego. Mr. Harwin also serves as chairman of the board of directors of Cogent Biosciences, Inc. (Nasdaq: COGT) and is a member of the board of directors of Apogee Therapeutics, Inc. (Nasdaq: APGE), Spyre Therapeutics, Inc. (Nasdaq: SYRE), Crescent Biopharma, Inc. (Nasdaq: CBIO), Damora Therapeutics, Inc. (Nasdaq: DMRA) and Paragon Therapeutics. Mr. Harwin served as a member of the board of directors of Viridian Therapeutics, Inc. (Nasdaq: VRDN) from October 2020 to March 2025. Mr. Harwin received a B.B.A. from Emory University.

We believe Mr. Harwin is qualified to serve as a member of the Board because of his experience serving as a director of biotechnology companies and as a manager of funds specializing in the area of life sciences.

Recommendation of the Board

THE BOARD OF DIRECTORS RECOMMENDS
A VOTE IN FAVOR OF EACH NAMED NOMINEE ABOVE

PROPOSAL 2

RATIFICATION OF APPOINTMENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Audit Committee has appointed PricewaterhouseCoopers LLP ("PwC") as Oruka's independent registered public accounting firm for the fiscal year ending December 31, 2026 and has further directed that management submit the appointment of PwC for ratification by our stockholders at the Annual Meeting. PwC has served as our auditor since the Merger Closing in 2024. Prior to the Merger Closing, PwC served as auditor of Pre-Merger Oruka. Representatives of PwC are expected to attend the Annual Meeting and will have an opportunity to make a statement if they so desire and are expected to be available to respond to appropriate questions.

Neither Oruka's Bylaws nor other governing documents or law require stockholder ratification of the appointment of PwC as Oruka's independent registered public accounting firm. However, the Audit Committee is submitting the appointment of PwC to stockholders for ratification as a matter of good corporate practice. If stockholders fail to ratify the selection, the Audit Committee will consider whether to retain PwC. Even if the appointment is ratified, the Audit Committee in its discretion may direct the appointment of a different independent registered public accounting firm at any time during the year if they determine that such a change would be in the best interests of Oruka and its stockholders.

Principal Accountant Fees and Services

The following is a summary of the audit fees billed and expected to be billed for the indicated fiscal year to Oruka by PwC, Pre-Merger Oruka's independent registered public accounting firm and Oruka's independent registered public accounting firm on and after August 30, 2024, and the fees billed by PwC for all other services rendered during the indicated fiscal year. All services associated with such fees on and after August 30, 2024 were pre-approved by our Audit Committee in accordance with the "Pre-Approval Policies and Procedures" described below.

	Fiscal Year ended December 31, 2025	Fiscal Year ended December 31, 2024
Audit Fees[1]	$ 1,050,000	$ 1,928,000
Audit-Related Fees[2]	—	—
Tax Fees[3]	—	—
All Other Fees[4]	2,000	2,000
Total	$ 1,052,000	$ 1,930,000

(1) Audit Fees consisted of fees and expenses covering the audit of our consolidated financial statements, reviews of our interim quarterly reports, accounting and financial reporting consultations, and the issuance of consents and comfort letters in connection with registration statement filings with the SEC.

(2) Consists of fees for review of accounting system transition.

(3) Consists of fees for professional services for tax compliance, tax advice and tax planning.

(4) All Other Fees consist of all other services and fees billed for an annual subscription to PwC's online resource library.

Pre-Approval Policies and Procedures

In connection with the Merger Closing, our Board and Audit Committee adopted a policy and procedures for the pre-approval of audit and non-audit services performed by our independent registered public accounting firm. These procedures generally approve the performance of specific services subject to a cost limit for all such services. This general approval is reviewed, and if necessary modified, at least annually. Management must obtain the specific prior approval of the Audit Committee for each engagement of our independent registered public accounting firm to perform other audit-related or non-audit services. The Audit Committee does not delegate its responsibility to pre-approve services performed by our independent registered public accounting firm to any member of management. The Audit Committee has delegated authority to the Audit Committee chair to pre-approve audit and non-audit services to be provided to us by our independent registered public accounting firm provided that the fees for such services do not exceed $100,000. Any pre-approval of services by the Audit Committee chair pursuant to this delegated authority must be reported to the Audit Committee at its next regularly scheduled meeting.

Recent Change in Independent Auditor

(a) Dismissal of Independent Registered Public Accounting Firm

KPMG LLP ("KPMG") served as the independent registered public accounting firm of ARCA prior to the consummation of the Merger. On August 30, 2024, KPMG was dismissed as the independent registered public accounting firm of the Company. The decision to dismiss KPMG was approved by the Audit Committee.

The reports of KPMG on the consolidated financial statements of the Company for the fiscal year ended December 31, 2023 did not contain an adverse opinion or disclaimer of opinion and was not qualified or modified as to uncertainty, audit scope or accounting principles.

During 2023, and the subsequent period from January 1, 2024 to August 30, 2024, there were (i) no disagreements (as defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions thereto) with KPMG on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreement, if not resolved to the satisfaction of KPMG, would have caused it to make reference to the subject matter of the disagreement in connection with its report and (ii) no reportable events (as described in Item 304(a)(1)(v) of Regulation S-K).

The Company provided KPMG with a copy of the disclosures made in this section and requested KPMG to furnish the Company with a letter addressed to the SEC stating whether it agrees with the statements made by the Company and, if not, stating the respects in which it does not agree. A copy of KPMG's letter to the SEC dated September 5, 2024 regarding these statements was filed as Exhibit 16.1 to the Company's Current Report on Form 8-K filed with the SEC on September 5, 2024.

(b) Appointment of New Independent Registered Public Accounting Firm

PwC served as the independent registered public accounting firm of Pre-Merger Oruka prior to the consummation of the Merger. On August 30, 2024, the Audit Committee engaged PwC as the independent registered public accounting firm of the Company.

During ARCA's two most recent fiscal years and the subsequent period from January 1, 2024 to August 30, 2024, neither ARCA nor anyone on its behalf consulted PwC regarding: (i) the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on ARCA's financial statements, and neither a written report nor oral advice was provided to ARCA that PwC concluded was an important factor considered by ARCA in reaching a decision as to any accounting, auditing or financial reporting issue; or (ii) any matter that was the subject of a disagreement (as defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions thereto) or a reportable event (as described in Item 304(a)(1)(v) of Regulation S-K).

Recommendation of the Board

THE BOARD OF DIRECTORS RECOMMENDS A VOTE IN FAVOR OF PROPOSAL 2.

PROPOSAL 3

NON-BINDING ADVISORY VOTE TO APPROVE NAMED EXECUTIVE OFFICER COMPENSATION

We are asking stockholders to indicate their support for our named executive officer compensation, as described in this Proxy Statement. This proposal, commonly known as a "say-on-pay" proposal, gives our stockholders the opportunity to express their view on compensation for our named executive officers. The say-on-pay vote is advisory and, therefore, not binding on us. Our Board and Compensation Committee value the opinions of our stockholders and review and consider the voting results when making decisions regarding our compensation program for our named executive officers. The say-on-pay vote is required pursuant to Section 14A of the Exchange Act.

Rationale and Scope of Proposal

Our Compensation Committee has structured our executive compensation program to achieve the following key objectives:

- attract and retain talented and experienced executives who strategically address our short-term and long-term needs;
- align the interests of our executives with stockholders by motivating executives to focus on activities and objectives that increase stockholder value and reward executives when stockholder value increases;
- compensate our executives in a manner that motivates them to manage our business to meet our short-term and long-term objectives and create stockholder value;
- retain executives whose knowledge, skills and performance are critical to our success; and
- foster a shared commitment among executives by aligning individual goals with those of the executive management team and our stockholders, while maintaining the highest standards of integrity, legal compliance, and patient safety in our research and development efforts.

We urge stockholders to read the "Executive Compensation" section of this Proxy Statement, which describes in more detail how our executive compensation program operates and is designed to achieve our compensation objectives. Our Compensation Committee and our Board believe that our policies and procedures are effective in achieving our goals and that the compensation of our named executive officers reported in this Proxy Statement has supported and contributed to our ability to conduct our business in the manner best suited for our stockholders.

This vote is not intended to address any specific item of compensation, but rather the overall compensation of our named executive officers and the philosophy, programs and practices described in this Proxy Statement.

In accordance with SEC rules, and as a matter of good corporate governance, we ask stockholders to approve the following advisory resolution:

> RESOLVED, that the stockholders of Oruka Therapeutics, Inc. approve, on an advisory basis, the compensation of the company's named executive officers disclosed in the Summary Compensation Table and the related compensation tables, notes and narratives in the proxy statement for the company's 2026 Annual Meeting of Stockholders.

Recommendation of the Board

THE BOARD OF DIRECTORS RECOMMENDS A VOTE IN FAVOR OF PROPOSAL 3.

CORPORATE GOVERNANCE

Our business affairs are managed under the direction of our Board. Our Board has adopted a set of Principles of Corporate Governance as a framework for the governance of the Company, which is posted on our website located at *https://ir.orukatx.com/corporate-governance* under "Governance Documents."

Our Governance Structure and Philosophy

Our governance practices reflect the environment in which we operate and are designed to support our mission to develop novel biologics designed to set a new standard for the treatment of chronic skin diseases. Our mission is to offer patients suffering from chronic skin diseases like plaque psoriasis the greatest possible freedom from their condition by achieving high rates of complete disease clearance with dosing as infrequently as once or twice per year. Oruka is a reasonably newly public, pre-revenue clinical stage biotechnology company in an evolving industry, with a focus on developing our candidate pipeline through both business development and internal research efforts, and, like other companies in the biotechnology industry, faces extreme stock price and volume fluctuations that are often unrelated or disproportionate to our operating performance. With these business environment considerations in mind, the Board believes our current governance structure enables the management team to act with deliberation while protecting the interests of all stockholders and supporting long-term value creation. This structure includes the following elements:

- **Classified board**: Our directors serve three-year terms, with approximately 1/3 of the Board (instead of the entire Board) elected at each annual meeting. This helps to provide stability and continuity, permitting directors to develop and share institutional knowledge and focus on the long term, and encourages stockholders to engage directly with the Board and management team regarding significant corporate transactions.
- **Supermajority voting**: The voting standard for most items is a majority of shares present and entitled to vote on the proposal, but 2/3 of the outstanding shares are needed to amend certain provisions of our Certificate of Incorporation and Bylaws and remove directors. This helps protect against a small group of stockholders acting to amend our governing documents or to remove directors for reasons that may not be in the best interests of all stockholders.
- **Plurality voting for directors**: Our directors are elected by a plurality of votes cast (instead of a majority of votes cast), meaning the nominees with the most votes are elected. This helps avoid potential disruption to the Board and management team as a result of a "failed election."
- **Stockholders cannot call special meetings or act by written consent**: Stockholders can propose business at each annual meeting (in accordance with our advance notice bylaws and Rule 14a-8) but cannot call a stockholder vote in between annual meetings or act by written consent. This helps avoid unnecessary diversion of Board and management time (potentially at the request of a limited number of stockholders acting to further short-term special interests) from executing on our long-term strategy.

Recognizing that the Company's operating environment continues to evolve and that governance practices should not be static as a matter of course, the Board annually evaluates our governance structure to confirm it remains in the best interests of the Company and stockholders and values input from our stockholders on this topic.

Independence of the Board of Directors

Our Board has reviewed the independence of all directors in light of each director's (or any family member's, if applicable) affiliations with the Company and members of management, as well as significant holdings of our securities and all other facts and circumstances that the Board has deemed relevant in determining the independence of each director. The Board has determined that each of the directors other than Lawrence Klein, our current Chief Executive Officer, including Kristine Ball, Carl Dambkowski, Peter Harwin, Samarth Kulkarni and Chris Martin, qualify as "independent directors" as defined by the Nasdaq listing rules.

Nasdaq listing rules have objective tests and a subjective test for determining who is an "independent director." The subjective test states that an independent director must be a person who lacks a relationship that, in the opinion of the Board, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. The Board has not established categorical standards or guidelines to make these subjective determinations but considers all relevant facts and circumstances.

All members of our Audit Committee, Compensation Committee and Nominating Committee must be independent directors under the Nasdaq listing rules. Members of the Audit Committee and Compensation Committee also must satisfy the independence criteria set forth in Rule 10A-3 and Rule 10C, respectively, under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Our Board has determined that all members of our Audit Committee, Compensation Committee and Nominating Committee satisfy the relevant independence requirements for such committees.

Diversity in Board Membership

Oruka actively seeks to achieve an appropriate level of diversity of perspectives, occupational and personal backgrounds in the membership of its Board and to assemble a broad range of skills, expertise and knowledge to benefit its business. The Nominating Committee and the full Board annually assess the composition of the Board, considering many dimensions, including industry experience, functional areas and skills (e.g., technology and finance), demonstrated leadership skills, character, independence, gender, geographic scope, public and private company experience, whether they are a member of an underrepresented community and director experience in the context of an assessment of the current and expected needs of the Board. The Nominating Committee reviews director candidates based on the Board's needs as identified through this assessment and considering the factors above. The Nominating Committee assesses its effectiveness in balancing these considerations in connection with its annual evaluation of the composition of the Board. Our Board includes directors with diverse gender and racial and ethnic backgrounds.

Board Leadership Structure

Our Board has designated Dr. Kulkarni to serve as Chair of the Board ("Chair"). Although our Bylaws do not require that we separate the Chief Executive Officer and Chair positions, our Board believes that having the positions be separate is the appropriate leadership structure for us at this time, as it helps facilitate independent Board oversight of management and allows the Chief Executive Officer to focus on strategy execution and managing the business while the Chair focuses on corporate governance and managing the Board.

Our Board recognizes that, depending on future circumstances, other leadership models, including combining the roles of Chief Executive Officer and Chair, may be appropriate and therefore periodically reviews its leadership structure. If a non-independent director serves as Chair, the independent directors will designate a lead independent director to preside at Board meetings in the Chair's absence, lead executive sessions, serve as a liaison between the Chair and the independent directors, and perform such additional duties as the Board may determine. The independent directors meet regularly in executive sessions without management present to promote open and effective communication.

The Board believes that its programs for overseeing risk, as described under "Role of the Board in Risk Oversight," would be effective under a variety of leadership frameworks. Accordingly, the Board's risk oversight function did not significantly impact its selection of the current leadership structure.

Role of the Board in Risk Oversight

The Board has an active role, as a whole and also at the committee level, in overseeing management of Oruka's risks and focuses its oversight on the most significant risks facing Oruka and on Oruka's processes to identify, prioritize, assess, manage and mitigate those risks. The Board regularly reviews information regarding Oruka's credit, liquidity and operations, as well as the risks associated with each. The Audit Committee is responsible for overseeing Oruka's practices with respect to risk assessment and management and the risks related to our financial statements and financial reporting process, compliance and information technology and cybersecurity. The Compensation Committee is responsible for overseeing the management of risks relating to Oruka's compensation policies and programs and human capital management practices. The Nominating Committee is responsible for overseeing the management of risks associated with director succession planning, the independence of the Board, potential conflicts of interest and other corporate governance practices. Our Board and its committees receive regular reports from members of Oruka's senior management on areas of material risk to the Company, including strategic, operational, financial, legal and regulatory risks. While our Board has an oversight role, management is principally tasked with direct responsibility for assessing and managing risks, including implementing processes and controls to mitigate their effects on the Company.

Meetings of the Board

The Board met four times in 2025. During 2025, each Board member attended 75% or more of the aggregate number of meetings of the Board and of the committees on which he or she served during the period in which he or she was on the Board or committee. We encourage each Board member to attend our annual stockholders' meeting. A number of members of the Board attended our 2025 Annual Meeting of Stockholders.

Information Regarding Committees of the Board

Our Board has a separately designated Audit Committee, Compensation Committee and Nominating Committee, each of which has the composition and responsibilities described below. Members serve on these committees until their resignation or until otherwise determined by our Board. Each of these committees is empowered to retain outside advisors as it deems appropriate, regularly reports its activities to the full Board and has a written charter, which is posted on our website located at *https://ir.orukatx.com/corporate-governance* under "Governance Documents."

Name	Audit Committee	Compensation Committee	Nominating and Corporate Governance Committee
Kristine Ball	Chair		X
Peter Harwin		X	Chair
Samarth Kulkarni		X	X
Cameron Turtle[(1)]	X	Chair	
Chris Martin[(2)]	X	Chair	
Carl Dambkowski	X		
Total # of meetings in 2025	4	3	2

(1) Resigned from the Board and its committees effective December 11, 2025.
(2) Appointed to the Board and its committees effective December 11, 2025.

Audit Committee

The primary responsibilities of the Audit Committee are to oversee our accounting and financial reporting processes, including the audits of the financial statements, and the internal and external audit processes. The Audit Committee also oversees the system of internal controls established by management and our compliance with legal and regulatory requirements. The Audit Committee is also responsible for the review, consideration and approval or ratification of related party transactions. The Audit Committee further oversees the independent auditors, including their independence and objectivity. The Audit Committee is empowered to retain outside legal counsel and other advisors as it deems necessary or appropriate to assist it in fulfilling its responsibilities and to approve the fees and other retention terms of the advisors.

Ms. Ball qualifies as an "audit committee financial expert," as that term is defined in the rules and regulations established by the SEC, and all members of the Audit Committee are "financially literate" under Nasdaq listing rules.

Report of the Audit Committee of the Board of Directors[1]

Management is responsible for Oruka's internal controls and the financial reporting process. The independent registered public accounting firm is responsible for performing an independent audit of Oruka's consolidated financial statements in accordance with the standards of the Public Company Accounting Oversight Board (United States) and to issue a report thereon. The Audit Committee's responsibility is to monitor and oversee these processes.

1 The material in this report is not "soliciting material," is not deemed "filed" with the SEC and is not to be incorporated by reference in any filing of Oruka under the Securities Act or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

In this context, in 2026, the Audit Committee met, reviewed and discussed the audited consolidated financial statements for the fiscal year ended December 31, 2025 with management and PricewaterhouseCoopers LLP ("PwC"). The Audit Committee has discussed with PwC the matters required to be discussed by the applicable requirements of the Public Company Accounting Oversight Board ("PCAOB") and the Securities and Exchange Commission. The Audit Committee has also received the written disclosures and the letter from PwC required by applicable requirements of the PCAOB regarding the independent accountants' communications with the Audit Committee concerning independence, and has discussed with the independent registered public accounting firm the accounting firm's independence.

Based on its discussions with management and the independent registered public accounting firm, the Audit Committee has recommended to the Board of Directors that the audited consolidated financial statements be included in Oruka's Annual Report on Form 10-K for the fiscal year ended December 31, 2025.

Kristine Ball (Chair)
Chris Martin
Carl Dambkowski

Compensation Committee

The primary responsibility of the Compensation Committee is to periodically review and approve the compensation and other benefits of our executive officers and directors. This includes reviewing and approving corporate goals and objectives relevant to the compensation of our Chief Executive Officer and other executive officers, evaluating the performance of these officers considering the goals and objectives and setting or recommending to the Board the officers' compensation. The Compensation Committee also administers and makes recommendations to the Board regarding equity incentive plans that are subject to the Board's approval, in addition to approving the grant of equity awards under those plans.

The Compensation Committee may delegate its duties and responsibilities to one or more subcommittees. The committee may also delegate authority to review and approve the compensation of our employees to certain of our executive officers. Even when the committee does not delegate authority, our executive officers will typically make recommendations to the committee regarding compensation to be paid to our employees and the size of equity awards under our equity incentive plans but will not be present during voting or deliberations on their own compensation. The committee has the authority to engage outside advisors, such as compensation consultants, to assist it in carrying out its responsibilities. The committee engaged Alpine Rewards LLC ("Alpine") in 2025 to provide advice regarding the amount and form of executive and director compensation. The committee reviewed Alpine's independence considering SEC rules and has affirmatively determined that the work performed by Alpine does not raise any conflict of interest. The committee did not receive any services from Alpine other than the compensation consulting services described above.

Nominating and Corporate Governance Committee

The Nominating and Corporate Governance Committee (the "Nominating Committee") is responsible for engaging in succession planning for our Board, developing and recommending to the Board criteria for identifying and evaluating qualified director candidates and making recommendations to the Board regarding candidates for election or reelection to the Board at each annual stockholders' meeting. In addition, the Nominating Committee is responsible for overseeing corporate governance matters. The Nominating Committee is also responsible for overseeing the structure, composition and functioning of the Board and its committees.

Director Nomination Process

The Nominating Committee is responsible for, among other things, engaging in succession planning for directors and identifying qualified individuals to become members of the Board to oversee management's execution of the Company's strategy and safeguard the long-term interests of stockholders. In this regard, the committee is charged with developing and recommending Board membership criteria to the Board for approval, evaluating the composition of the Board annually to assess the skills and experience that are currently represented on the Board and to assess the criteria that may be needed in the future, and identifying, reviewing the qualifications of and recommending potential director candidates.

In identifying potential candidates for Board membership, the Nominating Committee considers recommendations from directors, stockholders, management and others, including, from time to time, third-party search firms to assist it in locating qualified candidates.

Criteria for Board Membership

In assessing potential candidates for Board membership and in assessing Board composition, the Nominating Committee considers a wide range of factors and generally seeks to balance the following skills, experiences and backgrounds on the Board:

- **Leadership:** experience serving in a leadership role of an organization, including driving strategy execution, organizational growth and managing human capital;
- **Finance & Accounting:** experience or expertise in finance, accounting, financial reporting processes and capital markets;
- **Biotechnology Industry:** experience and knowledge of the biotechnology industry, in particular regarding therapeutics for autoimmune and inflammatory diseases;
- **Clinical Development:** experience driving the development of therapeutics, including the design and management of clinical trials;
- **Drug Approval Planning/Commercialization:** experience driving the planning process for new drug approvals, including medical affairs, and managing commercialization operations for approved drug candidates, including product manufacturing, pricing, reimbursement, marketing and distribution;
- **Corporate Governance:** experience, whether currently or in the past, serving on other public company boards of directors;
- **Operations & Administration:** experience managing corporate operations, including in the areas of human resources, legal, regulatory, public relations and product quality;
- **Portfolio Management:** experience managing investments or driving business development, including collaborations, licensing transactions, M&A and joint ventures/partnerships; and
- **Science & Research:** expertise or research experience in scientific disciplines related to biotechnology (e.g., biology, chemistry, medicine).

In addition to the above, the Nominating Committee generally believes it is important for all Board members to possess the highest personal and professional ethics, integrity and values, an inquisitive and objective perspective, a sense for priorities and balance, the ability and willingness to devote sufficient time and attention to Board matters, and a willingness to represent the long-term interests of all our stockholders.

In conducting this assessment, the Nominating Committee considers diversity as described under "Diversity in Board Membership" above. In the case of incumbent directors whose terms of office are set to expire, the Nominating Committee reviews these directors' overall service to Oruka during their terms, including the number of meetings attended, level of participation, quality of performance and any other relationships and transactions that might impair the directors' independence. In the case of new director candidates, once potential director candidates are identified, the committee, with the assistance of management, undertakes a vetting process that considers each candidate's background, independence and fit with the Board's priorities. As part of this vetting process, the committee, as well as other members of the Board and the CEO, may conduct interviews with the candidates. The Nominating Committee also determines whether the nominee is independent for Nasdaq purposes, which determination is based upon applicable Nasdaq listing standards, applicable SEC rules and regulations and the advice of counsel, if necessary. The Nominating Committee also conducts any appropriate and necessary inquiries into the backgrounds and qualifications of possible candidates after considering the function and needs of the Board. The Nominating Committee meets to discuss and consider the candidates' qualifications. If the committee

determines that a potential candidate meets the needs of the Board and has the desired qualifications, it recommends the candidate to the full Board for appointment or nomination and to the stockholders for election at the annual meeting.

Director Time Commitments

While Board members benefit from service on the boards of other companies and such service is encouraged, under the Board's Corporate Governance Guidelines, directors are encouraged to limit the number of other boards on which they serve so as not to interfere with their service as a director of the Company. At least annually, the Nominating Committee considers directors' service on other boards, and directors should advise the chair of the Nominating Committee before accepting a seat on the board of another for-profit organization.

Stockholder Recommendations for Directors

The Nominating Committee will consider director candidates recommended by stockholders. The Nominating Committee does not intend to alter the way it evaluates candidates, including the minimum criteria set forth above, based on whether or not the candidate was recommended by a stockholder. Stockholders who wish to recommend individuals for consideration by the Nominating Committee to become nominees for election to the Board may do so by delivering a written recommendation to the Nominating Committee at the following address: 855 Oak Grove Avenue, Suite 100, Menlo Park, CA 94025 by January 1 of the year in which such director is to be elected. Submissions must include the full name of the proposed nominee, a description of the proposed nominee's business experience for at least the previous five years, complete biographical information, a description of the proposed nominee's qualifications as a director and a representation that the nominating stockholder is a beneficial or record holder of Oruka's stock and has been a holder for at least one year. Any such submission must be accompanied by the written consent of the proposed nominee to be named as a nominee and to serve as a director if elected.

Stockholder Communications

Stockholders and other interested parties may communicate with our Board or a particular director by sending a letter addressed to the Board or a particular director to our Corporate Secretary at the address set forth on the first page of this Proxy Statement. These communications will be compiled and reviewed by our Corporate Secretary, who will determine whether the communication is appropriate for presentation to the Board or the particular director. The purpose of this screening is to allow the Board to avoid having to consider irrelevant or inappropriate communications (such as advertisements, solicitations and hostile communications).

To enable the Company to speak with a single voice, as a general matter, senior management serves as the primary spokesperson for the Company and is responsible for communicating with various constituencies, including stockholders, on behalf of the Company. Directors may participate in discussions with stockholders and other constituencies on issues where Board-level involvement is appropriate. In addition, the Board oversees the Company's stockholder engagement efforts.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics that establishes the standards of ethical conduct applicable to all our directors, officers and employees, including our principal executive officer, principal financial officer and principal accounting officer, or persons performing similar functions. It addresses, among other matters, compliance with laws and policies, conflicts of interest, corporate opportunities, regulatory reporting, external communications, confidentiality requirements, insider trading, proper use of assets and how to report compliance concerns. A copy of the code is available on our website located at *https://ir.orukatx.com/corporate-governance* under "Governance Documents." We intend to disclose any amendments to the code, or any waivers of its requirements, on our website to the extent required by applicable rules. The Audit Committee is responsible for applying and interpreting the code in situations where questions are presented to it.

Insider Trading Policy

We have adopted insider trading policies and procedures governing the purchase, sale and other transactions in Company securities by our directors, officers and employees, and other covered persons, as well as the Company itself, that we believe are reasonably designed to promote compliance with insider trading laws, rules and regulations, and Nasdaq listing rules, as applicable.

As part of these policies and procedures, we prohibit any employee, director or other covered person from engaging in short sales, transactions involving publicly traded options or other derivative securities based on the Company's securities, hedging transactions, margin accounts, pledges, or other inherently speculative transactions with respect to the Company's securities at any time.

Compensation Committee Interlocks

None of the members of our Compensation Committee has at any time during the prior three years been one of our officers or employees. None of our executive officers currently serves, or in the past fiscal year has served, as a member of the board or compensation committee of any entity that has one or more executive officers serving on our Board or Compensation Committee.

Director Compensation

The following table provides information for the year ended December 31, 2025 regarding all compensation awarded to, earned by or paid to each person who served as a non-employee director for some portion of 2025. Employees who served on our Board during 2025 did not receive additional compensation for such service:

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)[1][2]	Total ($)
Kristine Ball	60,000	153,067	213,067
Carl Dambkowski	47,500	153,067	200,567
Peter Harwin	56,000	153,067	209,067
Samarth Kulkarni	81,000	153,067	234,067
Cameron Turtle[3]	56,240	153,067	209,307
Chris Martin[4]	3,423	800,527	803,950

(1) These amounts are not cash compensation, but rather the aggregate fair value of the equity compensation granted to our non-employee directors during 2025. The aggregate fair value is computed in accordance with FASB ASC Topic 718. See Note 11 to our consolidated financial statements contained in our Annual Report on Form 10-K as filed with the SEC on March 12, 2026, regarding assumptions underlying valuation of equity awards. Each non-employee director was granted only one option award in 2025. See "Non-Employee Director Compensation Policy" below for a description of the option awards.

(2) As of December 31, 2025, the following non-employee directors each held stock options covering the following aggregate numbers of shares:

Name	Outstanding Option Awards (Shares) (#)
Kristine Ball	111,782
Carl Dambkowski	111,782
Peter Harwin	17,500
Samarth Kulkarni	217,492
Cameron Turtle[3]	12,520
Chris Martin[4]	35,000

(3) Resigned from the Board and its committees effective December 11, 2025.

(4) Appointed to the Board and its committees effective December 11, 2025.

Non-Employee Director Compensation Program

Non-employee members of the Board are eligible to receive cash and equity compensation in accordance with our non-employee director compensation program. This program provides for the following annual cash retainers:

Annual Cash Retainer	$	40,000
Annual Board Chair Retainer	$	30,000
Audit Committee Retainers:		
Chair	$	15,000
Non-Chair Member	$	7,500
Compensation Committee Retainers:		
Chair	$	12,000
Non-Chair Member	$	6,000
Nominating Committee Retainers		
Chair	$	10,000
Non-Chair Member	$	5,000

In connection with the Company's annual meeting of stockholders, each member of the Board will receive an annual grant of stock options to purchase 17,500 shares of common stock, which will vest in equal monthly installments over 12 months so long as such director joined the Board prior to January 1 of the year in which such annual meeting occurs.

In addition, in connection with a non-employee director's initial appointment to the Board, they will receive an initial grant of stock options to purchase 35,000 shares of common stock, which will vest in equal monthly installments over 36 months.

All members of the Board are also reimbursed for reasonable and documented out-of-pocket travel and lodging expenses incurred in connection with attending meetings and activities of the Board and its committees.

EXECUTIVE OFFICERS

Biographical and other information regarding our executive officers, who are appointed by the Board and serve at the Board's discretion, is set forth below. There are no family relationships among any of our directors or executive officers.

Name	Age (as of April 17)	Position
Lawrence Klein	43	President, Chief Executive Officer and Director
Joana Goncalves	52	Chief Medical Officer
Paul Quinlan	63	General Counsel and Corporate Secretary
Laura Sandler	48	Chief Operating Officer
Arjun Agarwal	50	Senior Vice President, Finance and Treasurer

Lawrence Klein's biography is included above under the section titled "Proposal 1 — Election of Directors."

Joana Goncalves, MBChB. Dr. Goncalves has served as the Chief Medical Officer of the Company since the Merger Closing and of Pre-Merger Oruka from April 2024 through the Merger Closing. Prior to joining Pre-Merger Oruka, Dr. Goncalves served as Chief Medical Officer of Cara Therapeutics, Inc. (Nasdaq: CARA), a biopharmaceutical company, from October 2018 to April 2024, where she was responsible for representing Cara Therapeutics in interactions with regulatory agencies, the investor and scientific communities and the board of directors, building multifunctional teams and developing the clinical development strategy in dermatological conditions. Prior to Cara, Dr. Goncalves held various positions at Celgene Corporation, a pharmaceutical company, which was later acquired by Bristol-Myers Squibb Company, from April 2014 to October 2018, where she most recently served as Vice President, Medical Affairs for Dermatology and Neurology and was instrumental in planning and executing medical support activities for a number of programs, including OTEZLA® for psoriasis. Prior to Celgene, Dr. Goncalves served as Vice President, Medical Strategy and Scientific Affairs at LEO Pharma Inc., the U.S. subsidiary of LEO Pharma A/S, a global healthcare company specializing in dermatology and critical care, from February 2012 to April 2014. She began her pharmaceutical career at Novartis Pharmaceuticals, working on a range of products across various therapeutic areas from 2001 to 2012. Dr. Goncalves received her MBChB from the University of Cape Town, South Africa.

Paul Quinlan. Mr. Quinlan has served as General Counsel and Corporate Secretary of the Company since the Merger Closing and of Pre-Merger Oruka from April 2024 through the Merger Closing. Prior to joining Pre-Merger Oruka, Mr. Quinlan served as General Counsel, Chief Compliance Officer and Corporate Secretary of CymaBay Therapeutics, Inc., a biopharmaceutical company, from October 2020 to March 2024, where he was responsible for the general supervision of the company's legal affairs. From December 2017 to February 2020, he served as General Counsel and Corporate Secretary of CymaBay, where he was responsible for the general supervision of the company's legal affairs. Prior to CymaBay, Mr. Quinlan served as General Counsel and Secretary, from 2010 to January 2018, and Chief Legal Officer from 2016 to January 2018, of TerraVia Holdings, Inc., a biotechnology company, where he was responsible for the general supervision of the company's legal affairs. Prior to joining TerraVia, Mr. Quinlan served as General Counsel of Metabolex, Inc., a biopharmaceutical company, from 2005 to 2010. Prior to joining Metabolex, Mr. Quinlan held various positions at Maxygen, Inc., a biopharmaceutical company, from 2000 to 2005. Prior to Maxygen, Mr. Quinlan practiced law at Cooley LLP and Cravath, Swaine, & Moore LLP. Mr. Quinlan received a law degree from Columbia Law School and an M.Sc. in Medical Biophysics from the University of Toronto.

Laura Sandler. Ms. Sandler has served as Chief Operating Officer of the Company since July 2025. She was Senior Vice President of Operations of the Company from the Merger Closing through July 2025 and was Senior Vice President of Operations of Pre-Merger Oruka from March 2024 through the Merger Closing. Prior to joining Pre-Merger Oruka, Ms. Sandler was, from September 2023 to March 2024, the Senior Vice President of Strategic Operations at Kelonia Therapeutics, Inc., a biopharmaceutical company, and was responsible for program leadership, program management, and quality assurance. She was an independent biopharmaceutical consultant from July 2022 to August 2023. Prior to that, from March 2017 to June 2022, Ms. Sandler held various positions at CRISPR Therapeutics AG, a biopharmaceutical company, ending as Senior Vice President of Development Operations, where she was the head of clinical execution and development operations for the company. From September 2013 to March 2017, Ms. Sandler led the development operations team for the Lyfgenia™ program at bluebird bio, Inc.,

a biopharmaceutical company. Earlier in her career, she held roles in project management and clinical operations at Ventrus Biosciences Inc., Novartis, IQVIA, and Medlmmune. Ms. Sandler earned her master's degree in public health from Boston University and has a bachelor's degree from MIT.

Arjun Agarwal. Mr. Agarwal has served as the Senior Vice President of Finance of the Company since the Merger Closing and of Pre-Merger Oruka from March 2024 through the Merger Closing. Prior to joining Pre-Merger Oruka, Mr. Agarwal served as VP of Finance at Jasper Therapeutics, Inc. (Nasdaq: JSPR), a biotechnology company, from June 2021 to March 2024, including through multiple financings and the company's successful transition to become a publicly traded entity. At Jasper, Mr. Agarwal was responsible for overseeing the company's finance and accounting functions. Before joining Jasper, Mr. Agarwal served as Vice President, Corporate Controller at Protagonist Therapeutics, Inc. (Nasdaq: PTGX), a biotechnology company, from August 2019 to June 2021, where he was responsible for overseeing the company's finance and accounting functions. Prior to joining Protagonist, Mr. Agarwal served in various roles of increasing responsibility at McKesson Corporation (NYSE: MCK), an international healthcare services company, from 2009 to 2019. Prior to McKesson, Mr. Agarwal worked at PricewaterhouseCoopers LLP, where he managed a portfolio of audit clients. He is a graduate of Sydenham College of Commerce and Economics at Mumbai University, India. He is a Certified Public Accountant (CPA) and a Chartered Accountant accredited by the Institute of Chartered Accountants of India.

EXECUTIVE COMPENSATION

This section provides information regarding the compensation of our principal executive officer, Dr. Klein, and our two other highest paid executive officers who were serving as executive officers on December 31, 2025, Dr. Goncalves and Mr. Quinlan. These individuals are collectively referred to herein as the "NEOs" or "named executive officers." We are a smaller reporting company, and the disclosures in this section reflect this status.

Name	Title
Lawrence Klein	Chief Executive Officer
Joana Goncalves	Chief Medical Officer
Paul Quinlan	General Counsel and Corporate Secretary

2025 Summary Compensation Table

The following table shows information regarding the compensation earned by the NEOs during the fiscal years ending December 31, 2025 and 2024, by our named executive officers.

Name and Principal Position[1]	Year	Salary ($)	Option Awards ($)[2]	Non-Equity Incentive Plan Compensation ($)[3]	All Other Compensation ($)[4]	Total ($)
Lawrence Klein	2025	624,000	2,275,390	446,160	10,500	3,356,050
Chief Executive Officer	2024	203,288	—	317,623	—	520,911
Joana Goncalves	2025	474,000	1,607,613	246,480	10,500	2,338,593
Chief Medical Officer	2024	155,854	—	162,132	—	317,986
Paul Quinlan	2025	474,000	1,607,613	246,480	10,500	2,338,593
General Counsel	2024	155,854	—	154,591	—	317,986

(1) The amounts reflected herein for 2024 for Drs. Klein and Goncalves and Mr. Quinlan do not include any compensation they received from Pre-Merger Oruka prior to the Merger.

(2) Represents the aggregate fair value of options granted for each fiscal year. The options vest in equal monthly installments over forty-eight months from January 1 of the applicable year, subject to the optionee's continued employment or service with Oruka. The options have a maximum term of 10 years, subject to earlier termination in certain situations related to cessation of employment or services. The aggregate fair value is computed in accordance with FASB ASC Topic 718. See Note 11 to our consolidated financial statements in our Annual Report on Form 10-K as filed on March 12, 2026, regarding assumptions underlying our valuation of equity awards.

(3) Amounts reported in this column represent the annual bonuses earned under the 2025 and 2024 annual bonus program, as described in more detail under "*Narrative to Summary Compensation Table — Elements of Compensation — Annual Bonus Program*" below.

(4) Company matching contributions under the Oruka 401(k) plan.

Narrative Disclosure to Summary Compensation Table

In December 2024, our Compensation Committee adopted a compensation philosophy to frame future compensation decisions for the Company. Under this philosophy, compensation positioning is used to attract and retain key employees for the Company's continued success and growth. While market data is helpful to the Compensation Committee in setting the compensation framework and guiding decisions, other factors such as Company strategy, stockholder feedback, tenure, performance and criticality are also considered. The compensation philosophy serves as the foundation to reinforce the Company's business strategy and desired culture, while balancing internal and external alignment.

Peer Group

In July 2024, Pre-Merger Oruka, in consultation with Alpine, the Compensation Committee's independent compensation consultant, established a peer group that focused on U.S.-based, pre-clinical or early clinical biopharma companies (with priority placed on companies with a similar therapeutic focus) with a market

capitalization ranging from $250 million to $2 billion and less than 100 employees. The peer group, which was used in making compensation decisions in connection with establishing executive compensation for 2025, included the following companies (the "Peer Group"):

Apogee Therapeutics	Astria Therapeutics	Cabaletta Bio
CARGO Therapeutics	Celldex Therapeutics	Contineum Therapeutics
Entrada Therapeutics	Janux Therapeutics	Kymera Therapeutics
Kyverna Therapeutics	Lexeo Therapeutics	Longboard Pharmaceuticals
Lyell Immunopharma	Pliant Therapeutics	Prime Medicine
Spyre Therapeutics	Structure Therapeutics	Third Harmonic Bio

The Peer Group is reviewed periodically and may be adjusted over time to reflect changes in the Company's size, stage of development, strategic focus and market capitalization, as well as changes in the peer companies themselves. While compensation of executive officers at companies included in the Peer Group is considered by the Compensation Committee in making its compensation decisions (the "Benchmark Analysis"), the Compensation Committee does not benchmark to any specific levels within the Peer Group for purposes of establishing the compensation levels for the Company's named executive officers.

Elements of Compensation

Base Salaries

Our Compensation Committee recognizes the importance of base salary as an element of compensation to provide our executive officers with steady cash flow during the year that is not contingent on short-term variations in our corporate performance. The setting of base salaries also includes an evaluation of each individual's job duties, responsibilities, performance and experience, as well as internal pay equity among the executive officer team. The Compensation Committee reviews base salaries at least annually and may recommend adjustment from time to time based on the results of that review. The Compensation Committee determines salary increases using a combination of relevant competitive market data, scope of responsibilities and assessment of individual performance.

The annual base salaries of Drs. Klein and Goncalves and Mr. Quinlan were established in connection with the consummation of their employment with Pre-Merger Oruka as a result of negotiations in the context of a competitive recruitment process and were adjusted in January 2025 to reflect merit adjustments. The annual base salaries as of December 31, 2025 for each of our NEOs were as follows: $624,000 for Dr. Klein and $474,000 for each of Dr. Goncalves and Mr. Quinlan.

Annual Bonus Program

We have an annual cash incentive plan under which cash incentives may be paid to each of our employees, including our executive officers, after the end of each calendar year. The Compensation Committee generally determines target bonuses based on Peer Group practices and each individual's job duties. For 2025, the target bonuses for each NEO, were set as follows: 55% of base salary for Dr. Klein and 40% of base salary for each of Dr. Goncalves and Mr. Quinlan.

The Compensation Committee and the Board established the corporate goals and performance targets for the 2025 annual bonus program, which were heavily weighted toward advancing our clinical development programs, with a primary focus on ORKA-001 and ORKA-002. Key objectives included specified progress in the ORKA-001 Phase 2a clinical trial and the Phase 1 clinical trials for both ORKA-001 and ORKA-002. In addition to clinical milestones, the 2025 corporate goals also included initiatives focused on securing sufficient funding to support our operations and building an appropriately scaled and efficient workforce to advance our strategic objectives.

The Compensation Committee reviewed our achievement against our 2025 corporate goals and determined the achievement to have been 130% of target, based on the achievement of all the goals, with substantial overperformance on several of the goals.

Based on our corporate performance, the 2025 annual bonuses awarded to our continuing NEOs were as follows: $446,160 for Dr. Klein and $246,480 for each of Dr. Goncalves and Mr. Quinlan.

Long-Term Incentives

We intend our equity incentive program to reward longer-term performance and to align the interests and incentives of our executive officers with those of our stockholders. We also believe that our equity incentive program, which currently consists predominantly of time-based stock options (or, for certain grants by Pre-Merger Oruka, time-based compensatory warrants), is an important retention tool for our employees, including our NEOs. The Compensation Committee believes that stock options, which require increased stock price performance for value realization, create a key connection between the interests of the NEOs and stockholders.

The Board, with respect to Dr. Klein, and the Compensation Committee, with respect to Dr. Goncalves and Mr. Quinlan, determined the individual equity awards granted to our NEOs in 2025 after considering a number of factors, including each executive's performance, role in achieving our current and future corporate objectives, anticipated difficulty of replacement, the competitive market for comparable positions, the retentive value of existing unvested equity holdings and internal equity among our senior management team. In addition, the Board and the Compensation Committee considered the 2025 Benchmark Analysis in informing their grant decisions and took into account Dr. Klein's request that 50% of the equity award the Board would otherwise have granted to him be reallocated among the senior management team. Based on these considerations, the 2025 equity awards consisted of stock options to purchase 230,000 shares of our common stock for Dr. Klein and 162,500 shares for each of Dr. Goncalves and Mr. Quinlan, with each award vesting in equal monthly installments over four years beginning January 1, 2025.

Offer Letters

In connection with their appointments, we entered into offer letters with each of Dr. Klein, Dr. Goncalves and Mr. Quinlan, each of which was amended and restated as of October 3, 2024 (for Dr. Klein) or October 1, 2024 (for Dr. Goncalves and Mr. Quinlan) following the Merger (collectively, the "Offer Letters"). The Offer Letters provided for each NEO's initial base salary, target annual bonus and initial equity incentive award. The Offer Letter with Dr. Klein also provided for periodic grants of stock options sufficient to maintain Dr. Klein's ownership at approximately 5% on a fully-diluted basis until Oruka raised an aggregate of $200 million in financing, which obligations were fully satisfied prior to the consummation of the Merger.

Under the Offer Letters, the NEOs are eligible for certain payments or benefits upon certain terminations of employment, as described under "*Additional Narrative Disclosure — Potential Payments Upon Termination or Change in Control*" below. The Offer Letter do not provide for tax gross-ups. Each of Dr. Klein, Dr. Goncalves and Mr. Quinlan is also party to our standard employee invention assignment, confidentiality and non-competition agreement, which, among other things, provides standard protections regarding our ownership of intellectual property, the confidentiality of our proprietary information, non-competition and non-solicitation.

Outstanding Equity Awards at Fiscal Year End

The following table presents information regarding outstanding stock options, compensatory warrants and restricted stock held by each NEO as of December 31, 2025.

	Option Awards				Stock Awards	
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)[1]
Lawrence Klein					461,683[2]	13,993,612
	678,547	949,966[3]	7.80	7/14/2034		
	52,708	177,292[4]	12.50	1/21/2035		
Joana Goncalves	91,734	133,329[5]	6.84	5/6/2034		
	79,830	116,662[5]	7.80	7/14/2034		
	37,240	125,260[4]	12.50	1/21/2035		
Paul Quinlan	95,234	133,329[6]	6.84	5/6/2034		
	41,665	58,331[6]	7.80	7/14/2034		
	37,240	125,260[4]	12.50	1/21/2035		

(1) The market value was determined by multiplying the number of shares by $30.31, the closing price of our common stock on December 31, 2025.

(2) These restricted shares vest as to approximately 17,757 shares monthly through February 26, 2028, subject to Dr. Klein's continued services to the Company.

(3) These compensatory warrants vest as to 25% on April 3, 2025 and in equal monthly installments thereafter through April 3, 2028, subject to Dr. Klein's continued services to the Company.

(4) These stock options vest as to 1/48 of the underlying shares monthly from January 1, 2025, subject to the named executive officer's continued services to the Company.

(5) These stock options and compensatory warrants vest as to 25% on April 18, 2025 and in equal monthly installments thereafter through April 18, 2028, subject to Dr. Goncalves' continued services to the Company.

(6) These stock options and compensatory warrants vest as to 25% on April 30, 2025 and in equal monthly installments thereafter through April 30, 2028, subject to Mr. Quinlan's continued services to the Company.

Additional Narrative Disclosures

Employee Benefits and Perquisites

Our NEOs are eligible to participate in our employee benefit plans, including our health and welfare plans, term life insurance, disability insurance, and 401(k) plan, on the same basis as all other employees. During 2025, we provided matching contributions under the 401(k) plan equal to 100% of the first 3% of eligible compensation deferred by participants, subject to applicable legal limits, for all employees, including the NEOs.

We generally do not provide perquisites or personal benefits to our NEOs, except in limited circumstances.

Potential Payments Upon Termination or Change in Control

Pursuant to the terms of the Offer Letters, in the event any of the NEO's employment is terminated by the Company without "cause" or as a result of a resignation for "good reason" (each, an "Involuntary Termination"), such NEO will, subject to the execution of a release in favor of the Company, receive: (i) severance payments equal to 12 months of base salary; (ii) Company-paid continuation coverage under the Company's group health plans for up to 12 months; and (iii) in the case of Dr. Klein, accelerated vesting of 30% of any outstanding time-based equity. However, if the Involuntary Termination is within three months before or 12 months after a change in control of the Company, the NEO will instead receive: (A) severance payments equal to 1.0 times (or, for Dr. Klein, 1.5 times) the

sum of the NEO's base salary and target bonus; (B) Company-paid continuation coverage under the Company's group health plans for up to 12 months (or, for Dr. Klein, up to 18 months); and (C) full acceleration of all equity awards. In addition, upon a NEO's separation due to the death or disability, the NEO's equity awards will accelerate in full.

As used in the Offer Letters:

- "Cause" generally means the NEO's (i) dishonest statements or acts with respect to the Company or any affiliate of the Company, or any current or prospective customers, suppliers, vendors or other third parties with which such entity does business that results in or is reasonably anticipated to result in material harm to the Company; (ii) conviction or plea of no contest to a felony or misdemeanor involving moral turpitude, deceit, dishonesty or fraud; (iii) failure to perform his or her duties or responsibilities, subject to a 30-day cure period; (iv) gross negligence, willful misconduct that results in or is reasonably anticipated to result in material harm to the Company; or (v) violation of any material provision of any agreement with the Company or any written Company policies.
- "Good reason" generally means (i) a material diminution in the named executive officer's base salary or target bonus (excluding across-the-board reductions of less than 10%); (ii) a material geographic relocation or requirement to change the named executive officer's remote work location; (iii) a material reduction in the named executive officer's duties, authority or responsibilities; (iv) the failure of the Company to obtain the assumption of the Offer Letter by a successor; or (v) the material breach of any agreement between the NEO and the Company, in each case, subject to standard notice and cure periods.

Clawback Policy

We maintain a Compensation Recoupment (Clawback) Policy, which is intended to comply with the requirements of Nasdaq Listing Standard 5608 implementing Rule 10D-1 under the Exchange Act. If the Company is required to prepare an accounting restatement of the Company's financial statements due to material non-compliance with any financial reporting requirement under the federal securities laws, the Company will recover, on a reasonably prompt basis, the excess incentive-based compensation received by any covered executive, including the NEOs, during the prior three fiscal years that exceeds the amount that the covered executive, including the NEOs, otherwise would have received had the incentive-based compensation been determined based on the restated financial statements.

Equity Grant Practices

Following the Merger, we generally grant annual equity awards in January of each year. We also grant equity as new hire awards, generally as of their date of employment commencement. During 2025 we only made equity awards through stock options. Beginning in 2026 we are providing annual equity awards and new hire equity awards through both stock options and restricted stock units. Employees, including the NEOs, may enroll to purchase shares under the terms of our 2024 Employee Stock Purchase Plan, as amended (the "ESPP"), with purchase dates generally occurring in June and December of each year using payroll deductions accumulated during the prior six-month period. During 2025, neither the Board nor the Compensation Committee took material nonpublic information into account when determining the timing and terms of stock options, and the Company did not time the disclosure of material nonpublic information for the purpose of affecting the value of executive compensation.

Pay Versus Performance

Our Compensation Committee approves and administers our executive compensation program to align executive compensation with stockholder interests by linking pay to performance. Our overall compensation program includes a mix of short-term and long-term components through our annual cash incentive plan and our equity incentive awards. As required by Item 402(v) of Regulation S-K, we are providing the following information

about the relationship between the compensation actually paid to our NEOs and certain aspects of our financial performance. We are a smaller reporting company pursuant to Rule 405 of the Securities Act and, as such, are only required to include information for the past three fiscal years in the table below.

Pay Versus Performance Table

Year	Summary Compensation Table Total for Mr. Bristow ($)[1]	Summary Compensation Table Total for Mr. Keuer ($)[1]	Summary Compensation Table Total for Dr. Klein ($)[1]	Compensation Actually Paid to Dr. Bristow ($)[3]	Compensation Actually Paid to Mr. Keuer ($)[3]	Compensation Actually Paid to Dr. Klein ($)[3]	Average Summary Compensation Total for Non-PEO NEOs ($)[2]	Average Compensation Actually Paid to Non-PEO NEOs ($)[3]	Total Stockholder Return Based on Initial Fixed $100 Investment ($)[4]	Net Income ($ in thousands)[5]
2025	N/A	N/A	3,356,050	N/A	N/A	16,022,952	2,338,593	5,414,235	106.57	(105,433)
2024	510,416	853,520	520,911	518,016	848,453	44,698,284	461,678	3,718,227	99.68	(83,724)
2023	358,800	N/A	N/A	290,864	N/A	N/A	361,937	323,666	71.73	(5,339)

(1) During years 2023, 2024 and 2025, the following individuals served as "principal executive officer" during the time periods set forth below:

Name	Dates as PEO During 2023 through 2025
Dr. Michael Bristow	January 1, 2023 through April 3, 2024
Thomas Keuer	April 3, 2024 through August 29, 2024
Dr. Lawrence Klein	August 29, 2024 through December 31, 2025

The dollar amounts reported in these columns represent the amount of total compensation reported for each of Drs. Klein and Bristow and Mr. Keuer (collectively, our "PEOs") for each covered fiscal year in the "Total" column of the Summary Compensation Table for each applicable year. Please refer to "Executive Compensation-Summary Compensation Table*"* above.

(2) The dollar amounts reported in this column represent the average amount of total compensation reported for our NEOs as a group (excluding our PEOs) for each covered fiscal year in the "Total" column of the Summary Compensation Table for each applicable year. Please refer to "Executive Compensation-Summary Compensation Table*"* above. The names of each NEO included for these purposes in each applicable year are as follows:

Year	Non-PEO NEOs
2025	Dr. Joana Goncalves, and Paul Quinlan
2024	Dr. Joana Goncalves, Paul Quinlan, and C. Jeffrey Dekker
2023	Thomas A. Keuer and C. Jeffrey Dekker

(3) The dollar amounts reported in these columns represent the amount of "compensation actually paid" to our PEOs or our NEOs as a group (excluding our PEOs), as computed in accordance with Item 402(v) of Regulation S-K, for each covered fiscal year. In accordance with these rules, these amounts reflect total compensation as set forth in the Summary Compensation Table, adjusted as shown below for 2025. Except as noted below, equity values are calculated in accordance with FASB ASC Topic 718, and the valuation assumptions used to calculate fair values did not materially differ from those disclosed at the time of grant. The dollar amounts do not reflect the actual amount of compensation earned or received by or paid to the PEOs during the applicable fiscal year.

	Dr. Bristow		Mr. Keuer	Dr. Klein		Average Non-PEO NEOs		
	2023	2024	2024	2024	2025	2023	2024	2025
Summary Compensation Table Total	$ 358,800	$ 510,416	$ 853,520	$ 520,911	$ 3,356,050	$ 361,937	$ 461,678	$ 2,338,593
Less, value of "Stock Awards" and "Option Awards" reported in Summary Compensation Table	—	$ (39,676)	$ (22,484)	—	$ (2,275,390)	—	$ (8,316)	$ (1,607,613)
Plus, year-end fair value of outstanding and unvested equity awards granted in the year[a]	—	—	—	$ 44,177,373	$ 4,631,919	—	$ 3,257,026	$ 3,272,535
Plus (less), year over year change in fair value of outstanding and unvested equity awards granted in prior years	$ (45,283)	—	—	—	$ 14,775,225	$ (15,718)	—	$ 2,272,225

	Dr. Bristow		Mr. Keuer	Dr. Klein		Average Non-PEO NEOs		
	2023	2024	2024	2024	2025	2023	2024	2025
Plus (less), change in fair value from last day of prior fiscal year to vesting date for equity awards granted in prior years that vested in the year[(b)]	$ (22,653)	$ 65,304	$ 24,059	—	$ (4,464,852)	$ (22,553)	$ 7,839	$ (861,505)
Less, prior year-end fair value for any equity awards forfeited in the year	—	$ (18,038)	$ (6,642)	—	—	—	—	—
Compensation Actually Paid	**$ 290,864**	**$ 518,016**	**$ 848,453**	**$ 44,698,284**	**$ 16,022,952**	**$ 323,666**	**$ 3,718,227**	**$ 5,414,235**

(a) For Dr. Klein and the average non-PEO NEOs as a group for 2024, includes the value of awards granted during 2024 by Pre-Merger Oruka that were assumed by the Company in connection with the Merger but that are not reflected in the Summary Compensation Table.

(b) For Dr. Bristow and Mr. Keuer and the average non-PEO NEOs as a group for 2024, the value as of the vesting date of the ARCA stock options that were accelerated and cashed out in connection with the Merger is based on the actual cash amount paid (representing the difference between $3.9489 and the applicable per share exercise price).

(4) Cumulative total stockholder return ("TSR") is calculated by dividing (a) the sum of (i) the cumulative amount of dividends during the measurement period, assuming dividend reinvestment, and (ii) the difference between our stock price at the end of the applicable measurement period and the beginning of the measurement period by (b) our stock price at the beginning of the measurement period. The beginning of the measurement period for each year in the table is December 31, 2022.

(5) The dollar amounts reported for 2023 represent the amount of net income (loss) reflected in ARCA's audited financial statements for 2023. The dollar amount reported for 2024 represents the amount of net income (loss) reflected in our audited financial statements for the period from February 6, 2024 (inception) to December 31, 2024, as reported in our Annual Report on Form 10-K and the dollar amount reported for 2025 represents the amount of net income (loss) reflected in our audited financial statements for 2025, as reported in our Annual Report on Form 10-K.

Analysis of Information Presented in the Pay Versus Performance Table

The information presented in the Pay Versus Performance table reflects different entities across the covered periods. The information for 2023 relates exclusively to ARCA, the information for 2024 reflects a combination of Pre-Merger Oruka, ARCA and the Company following the Merger, and the information for 2025 relates exclusively to the Company. Accordingly, compensation actually paid to Dr. Bristow for each year and to Mr. Keuer in 2024 relates to ARCA, while compensation actually paid to Dr. Klein reflects compensation following the Merger (and, for 2024, includes the year-end value of equity awards granted by Pre-Merger Oruka).

From 2023 to 2024, compensation actually paid to Dr. Bristow and Mr. Keuer (who was included as a non-PEO NEO in 2023) increased, generally aligning with the increase in TSR over such period, primarily due to the effect of stock price performance on the valuation of equity awards.

Compensation actually paid to Dr. Klein and the non-PEO NEOs for 2024 was significantly influenced by the year-end fair value of equity awards granted by Pre-Merger Oruka during 2024, which are not reflected in the Summary Compensation Table total and therefore do not have an offsetting reduction. This resulted in elevated compensation actually paid amounts for 2024 relative to other periods. While TSR performance as of December 31, 2024 positively impacted the value of these awards, the magnitude of compensation actually paid for 2024 primarily reflects these one-time valuation effects rather than a direct or consistent relationship with TSR.

From 2024 to 2025, compensation actually paid to Dr. Klein decreased significantly, while TSR increased over such period. The elevated compensation actually paid in 2024 was primarily attributable to the year-end fair value of equity awards granted by Pre-Merger Oruka. In contrast, compensation actually paid for 2025 was driven by (i) changes in the fair value of outstanding equity awards and (ii) the year-end fair value of equity awards granted during 2025, reflecting a more typical level of equity-based compensation following the one-time impacts in 2024. Although the increase in TSR during 2025 positively affected the valuation of these awards, compensation actually paid is not otherwise directly correlated with TSR as a performance measure, aside from the impact of stock price on equity award valuations.

Neither TSR nor net income (loss) was used as a direct performance measure in our executive compensation program for any of the periods presented. Accordingly, there is no direct relationship between compensation actually paid and net income (loss) in any year.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table provides information with respect to all our equity compensation plans in effect as of December 31, 2025.

Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Options (a)		Weighted Average Exercise Price of Outstanding Options (b)	Number of Securities Remaining Available for Future Issuances under Equity Compensation Plans (excluding securities reflected in column (a)) (c)
Equity Compensation Plans Approved by Security Holders:				
2024 Stock Incentive Plan	2,783,132	$	15.28	4,600,217[1]
2024 Employee Stock Purchase Plan	—		—	975,922[2]
2024 Equity Incentive Plan[3]	1,167,826	$	6.27	—
Equity Compensation Plans Not Approved by Security Holders:				
Non-Plan Compensatory Warrants[4]	3,029,510	$	7.80	—
Total	**6,980,468**	$	10.53	**5,576,139**

(1) The 2024 Stock Incentive Plan (the "2024 SIP") provides for an automatic increase in the number of shares reserved for issuance thereunder on January 1 of each year through and including January 1, 2034 equal to (a) 5% of number of issued and outstanding shares of common stock plus outstanding preferred stock and shares underlying unexercised pre-funded warrants on an as-converted basis (collectively, "Shares Outstanding") on December 31 of the immediately preceding year, or (b) a lesser amount as approved by the Compensation Committee each year. Pursuant to this provision, the number of shares available for issuance under the 2024 SIP increased by 3,354,715 shares on January 1, 2026.

(2) The 2024 Employee Stock Purchase Plan provides for an automatic annual increase in the number of shares reserved for issuance thereunder on January 1 of each year through and including January 1, 2034, equal to (a) 1% of the number of Shares Outstanding on December 31 of the immediately preceding year or (b) a lesser amount as approved by the Compensation Committee each year. Pursuant to this provision, the Compensation Committee approved a lesser amount of zero for the increase to be effective on January 1, 2026.

(3) Stock options granted by Pre-Merger Oruka under the 2024 Equity Incentive Plan were assumed by the Company in connection with the Merger. No further awards may be made under the 2024 Equity Incentive Plan.

(4) Non-plan compensatory warrants granted by Pre-Merger Oruka were assumed by the Company in connection with the Merger. No further non-plan compensatory warrants are expected to be granted.

CERTAIN INFORMATION ABOUT OUR COMMON STOCK

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth information, to the extent known by us or ascertainable from public filings, with respect to the beneficial ownership of our common stock as of February 15, 2026.

- each person or group of affiliated persons, who is known by us to be the beneficial owner of more than 5% of common stock;
- each of our directors and nominees;
- each of our named executive officers; and
- all of our current directors and executive officers as a group.

The column entitled "Percentage of Shares Outstanding Beneficially Owned" is based on a total of 49,096,889 shares of our common stock outstanding as of February 15, 2026.

Beneficial ownership is determined in accordance with the rules and regulations of the SEC and includes voting or investment power with respect to our common stock. Shares of our common stock subject to options that are currently exercisable or exercisable within 60 days of the date of this table are considered outstanding and beneficially owned by the person holding the options for the purpose of calculating the percentage ownership of that person but not for the purpose of calculating the percentage ownership of any other person. Except as otherwise noted, the persons and entities in this table have sole voting and investing power with respect to all the shares of our common stock beneficially owned by them, subject to community property laws, where applicable. Except as otherwise indicated in the table below, addresses of named beneficial owners are in care of Oruka Therapeutics, Inc., 855 Oak Grove Ave., Suite 100, Menlo Park, CA 94025.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Outstanding Beneficially Owned
5% Stockholders:		
Entities affiliated with Fairmount Funds Management LLC[(1)]	11,162,741	19.99%
FMR LLC[(2)]	7,261,384	14.79%
Entities affiliated with Venrock Healthcare Capital Partners[(3)]	4,909,619	9.99%
Entities affiliated with BlackRock, Inc.[(4)]	3,175,483	6.47%
Entities affiliated with Viking Global Investors LP[(5)]	2,666,690	5.43%
Named Executive Officers and Directors:		
Lawrence Klein[(7)]	1,354,020	2.71%
Joana Goncalves[(8)]	253,804	*
Paul Quinlan[(9)]	218,371	*
Samarth Kulkarni[(10)]	143,149	*
Peter Harwin[(1)]	11,162,741	19.99%
Carl Dambkowski[(11)]	179,695	*
Kristine Ball[(12)]	59,760	*
Chris Martin[(13)]	3,889	*
All current executive officers and directors as a group (10 persons)[(14)]	13,728,398	23.49%

* Less than 1%.

(1) Based on the Schedule 13D/A filed with the SEC on September 19, 2025. Consists of (i) (A) 1,131,954 shares of common stock, (B) 1,253,572 shares of common stock issuable upon the exercise of pre-funded warrants and (C) 6,203,907 shares of common stock issuable upon conversion of 74,447 shares of Series B Preferred Stock held by Fairmount Healthcare Fund II L.P. ("Fairmount Fund II") and (ii) 2,573,308 shares of common stock held by Fairmount Healthcare Co-Invest III L.P. ("Fairmount Fund III"). Excludes (i) 4,044,092 shares of common stock issuable upon the exercise of the pre-funded warrants and (ii) 5,224,242 shares of common stock issuable upon the conversion of 62,691 shares of Series B Preferred

Stock. The pre-funded warrants are subject to a beneficial ownership limitation of 9.99% and the shares of Series B Preferred Stock are subject to a beneficial ownership limitation of 19.99%, which such limitations restrict Fairmount Funds Management LLC ("Fairmount") and its affiliates from exercising that portion of the warrants and converting those shares of preferred stock that would result in Fairmount and its affiliates owning, after exercise or conversion, a number of shares of common stock in excess of the applicable ownership limitation. At such time as Fairmount and its affiliates beneficially own 9.0% or less of the shares of common stock, the beneficial ownership limitation applicable to the shares of Series B Preferred Stock will automatically reduce to 9.99%. Fairmount serves as investment manager for Fairmount Fund II and Fairmount Fund III. Fairmount Fund II and Fairmount Fund III have delegated to Fairmount the sole power to vote and the sole power to dispose of all securities held in Fairmount Fund II and Fairmount Fund III's portfolios. Because Fairmount Fund II and Fairmount Fund III have divested themselves of voting and investment power over the securities they hold and may not revoke that delegation on less than 61 days' notice, Fairmount Fund II and Fairmount Fund III disclaim beneficial ownership of the securities they hold. As managers of Fairmount, Peter Harwin and Tomas Kiselak may be deemed to have voting and investment power over the shares held by Fairmount Fund II and Fairmount Fund III. Fairmount, Peter Harwin and Tomas Kiselak disclaim beneficial ownership of such shares, except to the extent of any pecuniary interest therein. The address of the entities and individuals listed is 200 Barr Harbor Drive, Suite 400, West Conshohocken, PA 19428.

(2) Based on information contained in a Form 13F-HR filed with the SEC on February 17, 2026 for the period ending December 31, 2025. All of the shares listed in the table above are owned by funds or accounts managed by direct or indirect subsidiaries of FMR LLC, all of which shares are beneficially owned, or may be deemed to be beneficially owned, by FMR LLC, certain of its subsidiaries and affiliates, and other companies. Abigail P. Johnson is a Director, the Chairman and the Chief Executive Officer of FMR LLC. Members of the Johnson family, including Abigail P. Johnson, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other Series B shareholders have entered into a shareholders' voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders' voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR LLC. The address of FMR LLC is 245 Summer Street, Boston, MA 02210.

(3) Based on a Schedule 13G/A filed with the SEC on November 14, 2025. Consists of (i) 856,747 shares of common stock and pre-funded warrants exercisable for up to 158,157 shares of common stock held by Venrock Healthcare Capital Partners III, L.P. ("VHCP3"), (ii) 85,816 shares of common stock and pre-funded warrants exercisable for up to 15,819 shares of common stock held by VHCP Co-Investment Holdings III, LLC ("VHCPCo3"), and (iii) 3,205,865 shares of common stock and pre-funded warrants exercisable for up to 587,215 shares of common stock held by Venrock Healthcare Capital Partners EG, L.P. ("VHCPEG"). Excludes 172,458, 17,249 and 640,311 shares of common stock issuable upon the exercise of the pre-funded warrants held by VHCP3, VHCPCo3 and VHCPEG, respectively. The pre-funded warrants are subject to a beneficial ownership limitation of 9.99%, which such limitations restrict Venrock Healthcare Capital Partners and its affiliates from exercising that portion of the warrants that would result in Venrock Healthcare Capital Partners and its affiliates owning, after exercise, a number of shares of common stock in excess of the applicable ownership limitation. VHCP Management III, LLC ("VHCPM3") is the sole general partner of VHCP3 and the sole manager of VHCPCo3. VHCP Management EG, LLC ("VHCPM EG") is the sole general partner of VHCPEG. As voting members of VHCPM3 and VHCPM EG, Dr. Bong Koh and Nimish Shah may be deemed beneficial owners of any securities beneficially owned by VHCPM3 and VHCPM EG. The principal business address of each of these persons and entities is 7 Bryant Park, 23rd Floor, New York, NY 10018.

(4) Based solely on a Schedule 13G filed by BlackRock, Inc. on January 21, 2026, reporting sole power to vote 3,128,050 shares, sole power to dispose of 3,175,483 shares, shared power to vote no shares, and shared power to dispose of no shares as of December 31, 2025. Reflects the securities beneficially owned, or deemed to be beneficially owned, by certain business units of BlackRock, Inc. and its subsidiaries and affiliates. The principal business address of BlackRock, Inc. is 50 Hudson Yards New York, NY 10001.

(5) Based on a Schedule 13G/A filed with the SEC on September 24, 2025. Consists of (i) 1,600,014 shares of common stock held by Viking Global Opportunities Illiquid Investments Sub-Master LP ("VGOP") and (ii) 1,066,676 shares of common stock held by Viking Global Opportunities Drawdown (Aggregator) LP ("VGOD"). VGOP has the authority to dispose of and vote the shares directly owned by it, which power may be exercised by its general partner, Viking Global Opportunities Portfolio GP LLC ("Viking Opportunities GP") and by Viking Global Investors LP ("VGI"), which provides managerial services to VGOP. VGOD has the authority to dispose of and vote the shares directly owned by it, which power may be exercised by its general partner, Viking Global Opportunities Drawdown Portfolio GP LLC ("Drawdown GP") and by VGI, which provides managerial services to VGOD. O. Andreas Halvorsen, David C. Ott and Rose Shabet, as Executive Committee members of Viking Global Partners LLC (the general partner of VGI) and Viking Global Opportunities Parent GP LLC, the sole member of Viking Global Opportunities GP LLC (which is the sole member of Viking Opportunities GP) and Viking Global Opportunities Drawdown GP LLC (which is the sole member of Drawdown GP), have shared authority to direct the voting and disposition of investments beneficially owned by (i) VGI and Viking Opportunities GP and (ii) VGI and Drawdown GP. The principal business address of each of these persons and entities is 600 Washington Boulevard, Floor 11, Stamford, CT 06901.

(7) Includes (i) 408,412 shares of common stock, (ii) 4,794 shares of common stock issuable upon the vesting of restricted stock units within 60 days of the date of this table, (iii) 35,514 shares of common stock underlying restricted stock awards that vest within 60 days of the date of this table and (iv) 905,300 shares of common stock issuable upon the exercise of stock options that vest within 60 days of the date of this table. Does not include 71,907 shares of common stock issuable upon the vesting of restricted stock units that vest after such date nor 408,412 shares of common stock underlying restricted stock awards that vest after such date.

(8) Includes (i) 1,518 shares of common stock, (ii) 2,031 shares of common stock issuable upon the vesting of restricted stock units within 60 days of the date of this table and (iii) 250,255 shares of common stock issuable upon the exercise of stock options that vest within 60 days of the date of this table. Does not include 30,469 shares of common stock issuable upon the vesting of restricted stock units that vest after such date.

(9) Includes (i) 2,031 shares of common stock issuable upon the vesting of restricted stock units within 60 days of the date of this table and (ii) 216,340 shares of common stock issuable upon the exercise of stock options that vest within 60 days of the date of this table. Does not include 30,469 shares of common stock issuable upon the vesting of restricted stock units that vest after such date.

(10) Includes 143,149 shares of common stock issuable upon the exercise of stock options that vest within 60 days of the date of this table.

(11) Includes (i) 116,483 shares of common stock and (ii) 63,212 shares of common stock issuable upon the exercise of stock options that vest within 60 days of the date of this table.

(12) Includes 59,760 shares of common stock issuable upon the exercise of stock options that vest within 60 days of the date of this table.

(13) Includes 3,889 shares of common stock issuable upon the exercise of stock options that vest within 60 days of the date of this table.

(14) See notes (1), (7), (8), (9), (10), (11), (12) and (13) above. Also includes (i) 95,861 shares of common stock, (ii) 3,125 shares of common stock issuable upon the vesting of restricted stock units within 60 days of the date of this table, (iii) 8,878 shares of common stock underlying restricted stock awards that vest within 60 days of the date of this table and (iv) 245,105 shares of common stock issuable upon the exercise of stock options that vest within 60 days of the date of this table, in each case held by two executive officers who are not named executive officers.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires our directors, officers and persons who beneficially own more than 10% of a registered class of our equity securities to file with the Securities and Exchange Commission initial reports of ownership and reports of changes in ownership of our common stock and other equity securities. Based on our review of Forms 3, 4 and 5 filed with the Securities and Exchange Commission, our records and other information, we believe that, during the year ended December 31, 2025, all such persons timely filed all reports required under Section 16(a) of the Exchange Act, except for one Form 3 and one Form 4, which were filed by an investor approximately five days and ten days late, respectively, due to an administrative error.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Other than the compensation agreements and other arrangements disclosed above under "*Corporate Governance — Director Compensation*" and "*Executive Compensation*", we describe the transactions to which we or Pre-Merger Oruka were or are a party since January 1, 2024, in which the amount involved exceeds the lesser of $120,000 or one percent of the average of our or Pre-Merger Oruka's total assets at year-end for the last two completed fiscal years and in which our or Pre-Merger Oruka directors, executive officers, holders of more than 5% of our common stock, or members of their immediate family had a direct or indirect material interest.

Pre-Merger Oruka Transactions

Private Placements of Securities

Pre-Merger Oruka Series A Preferred Stock and Convertible Note Financing

On March 6, 2024, Oruka entered into a Convertible Note Purchase Agreement with Fairmount Healthcare Fund II, L.P. ("Fairmount Fund II"), whereby Oruka issued and sold to Fairmount Fund II (i) an aggregate of 20,000,000 shares of Pre-Merger Oruka Series A Preferred Stock at a purchase price of $0.15 per share and (ii) a convertible note (the "Convertible Note") with an initial principal amount of $25.0 million at an interest rate of 12% per annum, for aggregate gross proceeds of $28 million. Fairmount Fund II contributed the aggregate principal amount of $25.0 million and all accrued interest under the Convertible Note (unpaid accrued interest of $1.5 million divided by the conversion price of $66.62 ($5.55 prior to the impact of the Reverse Stock Split) per share) in exchange for Pre-Merger Oruka Common Stock and Pre-Merger Oruka pre-funded warrants in connection with the Pre-Merger Closing Financing (as defined below), immediately prior to the completion of the Merger. Fairmount Funds Management ("Fairmount") is the investment manager of Fairmount Fund II. Peter Harwin, one of our directors, is a managing member of Fairmount and Fairmount owns more than 5% of our common stock.

Pre-Merger Oruka Pre-Merger Closing Financing

On April 3, 2024, in connection with the execution of the Merger Agreement, Pre-Merger Oruka entered into the Subscription Agreement to consummate the Pre-Merger Closing Financing. Pursuant to the Subscription Agreement, the Financing Investors purchased 39,873,706 shares of Pre-Merger Oruka common stock and 9,664,208 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 and accrued interest on such note, which converted to 4,764,032 shares of Pre-Merger Oruka common stock), immediately prior to the Merger Closing and before the effect of the Reverse Stock Split. Three of the investors or their affiliates were beneficial holders of more than 5% of Pre-Merger Oruka's capital stock, and the table below sets forth the number of shares of Pre-Merger Oruka common stock and Pre-Merger Oruka pre-funded warrants purchased by such holders at the closing of the Pre-Merger Closing Financing.

Participant	Shares of Pre-Merger Oruka Common Stock	Pre-funded Warrants of Pre-Merger Oruka	Total Purchase Price
Entities affiliated with Fairmount	5,139,797	9,271,241	$ 79,907,282[1]
Entities affiliated with Venrock Healthcare Capital Partners	5,011,172	392,967	$ 29,996,067
Entities affiliated with FMR LLC	4,503,445	—	$ 24,999,974

(1) Includes $25.0 million of proceeds previously received by Pre-Merger Oruka from the issuance of the Convertible Note and accrued interest on such note, with the remainder of the purchase price paid in cash.

Company Transactions

September 2024 Private Placement

On September 11, 2024, the Company entered into a Securities Purchase Agreement (the "2024 SPA") with certain selling stockholders to consummate a private placement (the "2024 Private Placement"). Pursuant to the 2024 SPA, the selling stockholders purchased (i) an aggregate of 5,600,000 shares of Common Stock, at a price per share of $23.00, (ii) an aggregate of 2,439 shares of Series A Preferred Stock, at a price per share of $23,000.00, and (iii) pre-funded warrants to purchase an aggregate of 680,000 shares of Common Stock at a purchase price of $22.999 per pre-funded warrant, which represents the per share purchase price of the 2024 Private Placement Common Shares less the $0.001 per share exercise price for each pre-funded warrant, for an aggregate purchase price of approximately $200.5 million. Three of the participants or their affiliates were beneficial holders of more than 5% of the Company's capital stock, and the table below sets forth the number of shares of Common Stock, Series A Preferred Stock and pre-funded warrants purchased by such holders at the closing of the 2024 Private Placement.

Participant	Shares of Common Stock	Series A Preferred Stock	Pre-Funded Warrants	Total Purchase Price
Entities affiliated with FMR LLC.	2,105,000	830	—	$ 67,505,000
Entities affiliated with Venrock Healthcare Capital Partners.	150,000	200	300,000	$ 14,949,700
Entities affiliated with Fairmount.	275,000	160	—	$ 10,005,000

September 2025 Private Placement

On September 17, 2025, the Company entered into a Securities Purchase Agreement (the "2025 SPA") with certain selling stockholders to consummate a private placement (the "2025 Private Placement"). Pursuant to the 2025 SPA, the selling stockholders purchased (i) an aggregate of 10,933,405 shares of Common Stock, at a price per share of $15.00, and (ii) pre-funded warrants to purchase an aggregate of 1,066,666 shares of Common Stock at a purchase price of $14.999 per pre-funded warrant, which represents the per share purchase price of the 2025 Private Placement Common Shares less the $0.001 per share exercise price for each pre-funded warrant, for an aggregate purchase price of approximately $180 million. Three of the participants or their affiliates were beneficial holders of more than 5% of the Company's capital stock, and the table below sets forth the number of shares of Common Stock, and pre-funded warrants purchased by such holders at the closing of the 2025 Private Placement.

Participant	Shares of Common Stock	Pre-Funded Warrants	Total Purchase Price
Entities affiliated with FMR LLC.	1,640,010	—	$ 24,600,150
Entities affiliated with Venrock Healthcare Capital Partners . .	—	1,066,666	$ 15,998,923
Entities affiliated with Fairmount.	333,340	—	$ 5,000,100

Our Relationship with Paragon and Paruka

We are party to a number of agreements with Paragon and Paruka. Paragon and Paruka do not beneficially own more than 5% of our capital stock through their joint holdings of our Common Stock. Fairmount beneficially owns more than 5% of our capital stock, one of Fairmount's employees serves on our Board, and Fairmount 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, but is not the beneficial owner of Paragon's securities. Paruka is an entity formed by Paragon as a vehicle to hold equity in our Company to share profits with certain employees of Paragon.

In March 2024, Pre-Merger Oruka entered into the 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 us. The Option Agreements include two selected targets, IL-23 (ORKA-001) and IL-17A/F (ORKA-002). Under each of the Option Agreements, we had 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 potential products directed to the selected targets (each, an "Option"), with the exception of pursuing ORKA-001 for the treatment of inflammatory bowel disease. In September 2024, we exercised our Option to acquire the rights to ORKA-001 and executed the corresponding license agreement (the "IL-23 License Agreement") on December 17, 2024. In December 2024 we exercised our Option to acquire the rights to ORKA-002 and executed the corresponding license agreement (the IL-17A/F License Agreement) on February 4, 2025. Under each license agreement we are 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 a low single-digit percentage royalty for antibody products beginning on the first commercial sale in each program. From time to time, we can choose to add additional targets to the collaboration by mutual agreement with Paragon. During 2025, we paid two $1.5 million milestone payments and one $2.5 million milestone payment related to the development of the ORKA-001 and ORKA-002 programs as research and development expense in our consolidated statements of operations and comprehensive loss for the year ended December 31, 2025. As of December 31, 2025, this amount is included under related party accounts payable and other current liabilities on the consolidated balance sheet.

In December 2025 we entered into a Letter Agreement with Paragon with respect to our ORKA-003 program. In connection with the Letter Agreement, we paid Paragon $750,000 for an option to acquire a worldwide exclusive license for the ORKA-003 program and issued a warrant to purchase 375,000 shares of Common Stock. This warrant was granted in December 2025 with an exercise price of $30.18 per share, the fair market value of our Common Stock on the date of grant.

Indemnification Agreements and Insurance

We have entered into an indemnification agreement with each of our directors and executive officers and purchased directors' and officers' liability insurance. The indemnification agreements require us to indemnify our directors and executive officers to the fullest extent permitted under Delaware law.

Review, Approval or Ratification of Transactions with Related Parties

Our Board has adopted a written related person transactions policy. Under this policy, our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of our Common Stock, and any members of the immediate family of and any entity affiliated with any of the foregoing persons, are not permitted to enter into a material related person transaction with us without the review and approval of our Audit Committee, or a committee composed solely of independent directors in the event it is inappropriate for our Audit Committee to review such transaction due to a conflict of interest. The policy provides that, subject to limited exceptions, any transaction, arrangement or relationship or series of similar transactions, arrangements or relationships in which (1) the aggregate amount involved since the beginning of the Company's last completed fiscal year exceeds or is expected to exceed $120,000, (2) the Company or any of our subsidiaries is a participant, and (3) any related person has or will have a direct or indirect interest, will be presented to our Audit Committee for review, consideration and approval. In approving or rejecting any such proposal, our Audit Committee will consider the material facts and other factors it deems appropriate, including, but not limited to, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related person's interest in the transaction.

OTHER MATTERS

Stockholder Proposals and Director Nominations for Next Year's Annual Meeting

Pursuant to Rule 14a-8 of the Exchange Act, stockholders who wish to submit proposals for inclusion in the proxy statement for the 2027 Annual Meeting of Stockholders must send such proposals to our Corporate Secretary at the address set forth on the first page of this Proxy Statement. Such proposals must be received by us as of the close of business (6:00 p.m. Eastern Time) on December 18, 2026 and must comply with Rule 14a-8 of the Exchange Act. The submission of a stockholder proposal does not guarantee that it will be included in the proxy statement.

As set forth in our Bylaws, if a stockholder intends to make a nomination for director election or present a proposal for other business (other than pursuant to Rule 14a-8 of the Exchange Act) at the 2027 Annual Meeting of Stockholders, the stockholder's notice must be received by our Corporate Secretary at the address set forth on the first page of this Proxy Statement no earlier than the 120th day and no later than the close of business on the 90th day before the anniversary of the last annual meeting; provided, however, that if the date of the annual meeting is more than 30 days before or more than 60 days after such anniversary date, the stockholder's notice must be delivered not earlier than the close of business on the 120th day prior to such annual meeting and not later than the close of business on the later of the 90th day prior to such annual meeting or the 10th day following the date on which the first public announcement of the date of such annual meeting is made by the Company. Therefore, unless the 2027 Annual Meeting of Stockholders is more than 30 days before or more than 60 days after the anniversary of the Annual Meeting, notice of proposed nominations or proposals (other than pursuant to Rule 14a-8 of the Exchange Act) must be received by our Corporate Secretary no earlier than February 2, 2027 and no later than the close of business on March 4, 2027. Any such director nomination or stockholder proposal must be a proper matter for stockholder action and must comply with the terms and conditions set forth in our Bylaws (which includes the timing and information required under Rule 14a-19 of the Exchange Act). If a stockholder fails to meet these deadlines or fails to satisfy the requirements of Rule 14a-4 of the Exchange Act, we may exercise discretionary voting authority under proxies we solicit to vote on any such proposal as we determine appropriate. We reserve the right to reject, rule out of order or take other appropriate action with respect to any nomination or proposal that does not comply with these and other applicable requirements.

Delivery of Documents to Stockholders Sharing an Address

A number of brokerage firms have adopted a procedure approved by the SEC called "householding." Under this procedure, certain stockholders who have the same address and do not participate in electronic delivery of proxy materials will receive only one copy of the proxy materials, including this Proxy Statement, the Notice and our Annual Report on Form 10-K for the year ended December 31, 2025, until such time as one or more of these stockholders notifies us that they wish to receive individual copies. This procedure helps to reduce duplicate mailings and save printing costs and postage fees, as well as natural resources. If you received a "householding" mailing this year and would like to have additional copies of the proxy materials mailed to you, please send a written request to our Corporate Secretary at the address set forth on the first page of this Proxy Statement, or call (650) 606-7910, and we will promptly deliver the proxy materials to you. Please contact your broker if you received multiple copies of the proxy materials and would prefer to receive a single copy in the future, or if you would like to opt out of "householding" for future mailings.

Availability of Additional Information

We will provide, free of charge, a copy of our Annual Report on Form 10-K for the year ended December 31, 2025, including exhibits, on the written or oral request of any stockholder of the Company. Please send a written request to our Corporate Secretary at the address set forth on the first page of this Proxy Statement, or call the number above.