

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

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 26, 2026

Oruka Therapeutics, Inc.
(Exact name of Registrant as Specified in its Charter)

Delaware (State or other jurisdiction of incorporation)	000-22873 (Commission File Number)	36-3855489 (IRS Employer Identification No.)
855 Oak Grove Avenue Suite 100 Menlo Park, California (Address of principal executive offices)		94025 (Zip Code)

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

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.001 par value	ORKA	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

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. ☐

Item 7.01 Regulation FD Disclosure.

On October 26, 2026, Oruka Therapeutics, Inc. (“Oruka” or the “Company”) issued a press release and made publicly available a data presentation announcing Week 16 results from its Phase 2b EVERLAST-B clinical trial of ORKA-001, an investigational, half-life extended IL-23p19 monoclonal antibody, in patients with moderate-to-severe plaque psoriasis (“PsO”). Oruka will host a conference call and webcast today, Monday, October 26, 2026, at 8:00 a.m. Eastern Time, to discuss the results.

The information in this Item 7.01 of this Current Report on Form 8-K, including the information in the press release and presentation attached as Exhibits 99.1 and 99.2 to this Current Report on Form 8-K, is furnished pursuant to Item 7.01 of Form 8-K and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section. Furthermore, the information in this Item 7.01, including the press release and presentation attached as Exhibits 99.1 and 99.2, shall not be deemed incorporated by reference in any filing of the Company under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

On October 26, 2026, Oruka announced Week 16 results from its Phase 2b EVERLAST-B clinical trial of ORKA-001 in patients with moderate-to-severe PsO.

EVERLAST-B Phase 2b Key 16-Week Results

EVERLAST-B is a randomized, double-blind, placebo-controlled Phase 2b clinical trial evaluating the safety, efficacy and pharmacokinetics of ORKA-001 in patients with moderate-to-severe PsO. The trial enrolled 187 patients randomized 1:1:1:1 to receive 37.5 mg of ORKA-001 at Week 0 (“Low Dose”), 300 mg at Weeks 0 and 4 (“Mid Dose”), 600 mg at Weeks 0 and 4 (“High Dose”), or placebo. The primary endpoint is the proportion of patients achieving PASI 100 at Week 16. At Week 28, patients who achieve PASI 100 will be re-randomized 1:1 to receive either 600 mg of ORKA-001 once yearly, with the initial maintenance dose planned for Week 52, or matching placebo. Patients who do not achieve PASI 100 at Week 28 will receive 300 mg of ORKA-001 every six months.

Initial 16-week findings from EVERLAST-B include efficacy results, which compare favorably versus standard of care across endpoints based on cross-trial comparisons, as well as a favorable safety profile consistent with the IL-23p19 inhibitor class.

At Week 16, the percentage of patients achieving the listed efficacy endpoints was as follows:

Week 16 endpoint	Placebo (N=47)	Low Dose (N=47)	Mid Dose (N=47)	High Dose (N=46)
PASI 100	0%	43%	44%	61%
PASI 90	0%	70%	85%	86%
IGA 0/1	0%	74%	85%	86%

The primary endpoint was achieved by 61% of patients in the 600 mg group, compared with 0% of patients receiving placebo (p<0.0001). Efficacy results in the 600 mg group were generally consistent with those observed in EVERLAST-A.

ORKA-001 continued to show a favorable safety and tolerability profile. At least one treatment-emergent adverse event (“TEAE”) was reported in 39% of patients in the 600 mg group and 43% of patients receiving placebo. No serious TEAEs occurred in the 600 mg group. Three serious TEAEs occurred among patients in the ORKA-001 treatment groups receiving lower doses; none was considered treatment-related. No injection site reactions were reported among patients receiving ORKA-001. The most common TEAEs observed were upper respiratory tract infection and headache.

The trial is ongoing, and longer-term data, including durability of response and additional safety follow-up, are expected in the second half of 2027.

Oruka plans to initiate Phase 3 trials of ORKA-001 in moderate-to-severe PsO in the first half of 2027, with the High Dose (600 mg), subject to regulatory interactions, and expects to report 52-week results from EVERLAST-A in December 2026. The Company also expects to report Week 16 results from the ORKA-002 Phase 2 PsO trial in the first quarter of 2027.

Second Quarter 2026 Financial Results

Cash Position: As of June 30, 2026, Oruka had cash, cash equivalents, and marketable securities of \$1.1 billion. The Company expects that its cash, cash equivalents, and marketable securities will be sufficient to fund operations through an anticipated BLA filing for ORKA-001 and continued development of ORKA-002.

Forward-looking Statements

This Current Report on Form 8-K contains certain statements that may constitute “forward-looking statements” within the meaning of the federal securities laws, including for purposes of the safe harbor provisions under the United States Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, statements regarding Oruka’s development programs and business strategy; the planned timing, progress and results of clinical trials, including EVERLAST-A, EVERLAST-B and the ORKA-002 Phase 2 trial; planned Phase 3 trials and related regulatory interactions; anticipated clinical data readouts; the potential clinical profile of ORKA-001, including its safety, efficacy, pharmacokinetics, dosing regimen and durability; the potential for annual dosing; expected cash runway; and illustrative estimates of future product sales and market opportunity included in the presentation.

Words such as “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 Oruka’s current expectations and beliefs concerning future developments and their potential effects. There can be no assurance that future developments affecting Oruka will be those that have been anticipated. Forward-looking statements involve risks and uncertainties, some of which are beyond Oruka’s control, that may cause actual results or performance to be materially different from those expressed or implied. These risks and uncertainties include those described under “Risk Factors” and “Cautionary Note Regarding Forward-Looking Statements” in Oruka’s most recent Annual Report on Form 10-K and other periodic or current reports filed with the Securities and Exchange Commission. Readers are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date made. Oruka does not assume any obligation to update forward-looking statements except as required by law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated October 26, 2026
99.2	Presentation, dated October 26, 2026
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

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

Oruka Therapeutics, Inc.
(Registrant)

Date: October 26, 2026

By: /s/ Paul Quinlan
Name: Paul Quinlan
Title: General Counsel

Oruka Therapeutics Announces Positive Week 16 Results for ORKA-001 from the Ongoing EVERLAST-B Trial in Moderate-to-Severe Psoriasis

61% PASI 100 and 86% PASI 90 in the ORKA-001 high-dose (600 mg) group, highly similar to EVERLAST-A

Continued favorable safety and tolerability profile consistent with the IL-23p19 class

ORKA-001 on track to advance into Phase 3 trials in 1H 2027

52-week EVERLAST-A results on track for December 2026

ORKA-002 16-week results from ORCA-SURGE Phase 2 in psoriasis on track for 1Q 2027

Management to host conference call today at 8:00 a.m. ET

MENLO PARK, Calif., October 26, 2026 (GLOBE NEWSWIRE) -- Oruka Therapeutics, Inc. (Oruka) (Nasdaq: ORKA), a clinical-stage biotechnology company developing novel biologics designed to set a new standard for the treatment of chronic skin diseases including plaque psoriasis (PsO) and hidradenitis suppurativa (HS), today announced positive Week 16 results from its EVERLAST-B Phase 2b trial of ORKA-001, a novel half-life extended IL-23p19 monoclonal antibody, in moderate-to-severe PsO.

“We are incredibly pleased with the remarkable profile of ORKA-001 observed to date, with highly consistent results achieved across EVERLAST-B and EVERLAST-A. These results further solidify our confidence that ORKA-001 could become the preferred medicine for psoriasis, with high rates of complete skin clearance, a favorable safety profile, and potential for dosing once to twice per year,” said Joana Goncalves, MBChB, Chief Medical Officer of Oruka. “The data shared today support our next step: engaging with regulatory agencies as we advance ORKA-001 towards Phase 3 trials, which we plan to initiate in the first half of next year.”

“These results suggest ORKA-001 is likely to be the most effective IL-23-targeting biologic to date,” said Joel Gelfand, MD, MSCE, FAAD, James J. Leyden Professor of Dermatology and Epidemiology at the University of Pennsylvania and lead investigator for EVERLAST-B. “Virtually all patients could expect to have a very good response, and the majority could expect to achieve completely clear skin within just 16 weeks. The potential for these effects to be long lasting, with just one or two doses a year, would be a paradigm shift in moderate-to-severe psoriasis management, allowing for the trifecta of clear skin, convenience, and excellent safety that would further elevate the standard of care we can offer our patients.”

EVERLAST-B is a randomized, double-blind, placebo-controlled Phase 2b trial evaluating the safety, efficacy, and pharmacokinetics of ORKA-001 in patients with moderate-to-severe PsO. The trial is being conducted across 36 sites in the United States, Canada, and Europe. Less than 30% of these sites participated in EVERLAST-A. EVERLAST-B enrolled 187 patients randomized 1:1:1:1 to receive 37.5 mg ORKA-001 at Week 0 (low dose), 300 mg ORKA-001 at Weeks 0 and 4 (mid dose), 600 mg ORKA-001 at Weeks 0 and 4 (high dose), or placebo. The primary endpoint is PASI 100 at Week 16. At Week 28, patients receiving ORKA-001 who have achieved PASI 100 will be re-randomized 1:1 to either 600 mg ORKA-001 once yearly or placebo. Patients who have not achieved PASI 100 will receive 300 mg ORKA-001 every six months. The study continues through Week 100 to assess durability of response, maintenance dosing, and long-term safety.

Efficacy

Efficacy increased in a dose-dependent manner across ORKA-001 treatment groups, with the high-dose (600 mg) group outperforming both lower dose groups on complete skin clearance. 61% of patients in the high-dose group achieved the primary endpoint of PASI 100 at Week 16, compared to 0% of patients receiving placebo (p<0.0001). The ORKA-001 high-dose group demonstrated high response rates across secondary endpoints, including 86% of patients achieving PASI 90 and IGA 0/1, consistent with the results observed in EVERLAST-A.

Week 16	Placebo (N=47)	Low dose (N=47)	Mid dose (N=47)	High dose (N=46)
PASI 100	0%	43%	44%	61%
PASI 90	0%	70%	85%	86%
IGA 0/1	0%	74%	85%	86%

Safety

ORKA-001 continues to be well tolerated, with a safety profile consistent with the IL-23p19 class. The overall rate of treatment-emergent adverse events (TEAEs) was comparable across groups, with 39% of patients in the high-dose group experiencing at least one TEAE, versus 43% of participants receiving placebo. The only TEAEs occurring in $\geq 5\%$ of patients treated with ORKA-001 were upper respiratory tract infection and headache, occurring at rates similar to those seen with approved IL-23 inhibitors. No dose-dependent trends in adverse events were observed across ORKA-001 treatment groups, and no injection-site reactions occurred in any patients who received ORKA-001.

Week 0-16	Placebo (N=47)	Low dose (N=47)	Mid dose (N=47)	High dose (N=46)	All ORKA-001 (N=140)
≥ 1 TEAE, n (%)	20 (43%)	22 (47%)	28 (60%)	18 (39%)	68 (49%)
≥ 1 serious TEAE, n (%)	2 (4%)	1 (2%)	2 (4%)	-	3 (2%)
≥ 1 severe TEAE, n (%)	2 (4%)	1 (2%)	2 (4%)	-	3 (2%)
Discontinuation due to TEAE, n (%)	1 (2%)	1 (2%)	1 (2%)	-	2 (1%)
Most frequent TEAEs, n (%)					
Upper respiratory tract infection	4 (9%)	5 (11%)	9 (19%)	6 (13%)	20 (14%)
Headache	1 (2%)	2 (4%)	3 (6%)	3 (7%)	8 (6%)
Injection site reactions, n (%)	1 (2%)	-	-	-	-

No serious TEAEs occurred in the high-dose group. Serious TEAEs occurring in the other groups were kidney stones, miscarriage, psoriasis, substance-induced psychotic disorder, and syncope following a blood draw and jaw fracture. None were considered treatment related.

Upcoming Milestones for ORKA-001

Based on the results from the EVERLAST clinical program, the company intends to discuss Phase 3 plans with regulatory authorities. Pending results from those discussions, Oruka plans to initiate Phase 3 trials of ORKA-001 in moderate-to-severe PsO in the first half of 2027 with the high dose (600 mg). In addition, Oruka expects to share 52-week results from EVERLAST-A in December 2026, as well as 52-week results from EVERLAST-B in the second half of 2027.

Webcast Details

Oruka Therapeutics' live webcast of the EVERLAST-B results will begin today at 8:00 a.m. ET. The live webcast can be accessed via this link, or through the Investors section on the company's website at <https://ir.orukatx.com/news-events/events-presentations>. A replay of the webcast will be available following the call.

About Oruka Therapeutics

Oruka Therapeutics is developing novel biologics designed to set a new standard for the treatment of chronic skin diseases. Oruka's mission is to offer patients suffering from inflammatory diseases like plaque psoriasis and hidradenitis suppurativa the greatest possible freedom from their condition by achieving high rates of disease clearance with dosing as infrequently as once or twice a year. For more information, visit www.orukatx.com and follow Oruka on LinkedIn.

Forward-Looking Statements

Certain statements in this press release, other than statements of historical fact, are “forward-looking statements” within the meaning of the federal securities laws, including the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, statements regarding: the potential therapeutic benefits, efficacy, safety, tolerability, durability of response and dosing profile of ORKA-001; the potential for ORKA-001 to provide durable disease control with infrequent dosing; the planned conduct, progress, timing and results of the EVERLAST-A and EVERLAST-B trials; and the anticipated timing of clinical data readouts and ORKA-001 Phase 3 trial commencement. These forward-looking statements are based on Oruka’s current expectations and beliefs concerning future developments and their potential effects. There can be no assurance that future developments affecting Oruka will be those that have been anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond Oruka’s 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. These risks and uncertainties include, but are not limited to, those uncertainties and factors described under the heading “Risk Factors” and “Cautionary Note Regarding Forward-Looking Statements” in Oruka’s most recent filings with the Securities and Exchange Commission (SEC), including its Annual Report on Form 10-K and Quarterly Reports on Form 10-Q. Should one or more of these risks or uncertainties materialize, or should any of Oruka’s assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. Nothing in this press release should be regarded as a representation by any person that the forward-looking statements set forth therein will be achieved or that any of the contemplated results of such forward-looking statements will be achieved. You should not place undue reliance on forward-looking statements in this press release, which speak only as of the date they are made and are qualified in their entirety by reference to the cautionary statements herein and in Oruka’s SEC filings. Oruka does not undertake or accept any duty to make any updates or revisions to any forward-looking statements except as required by applicable law.

Investor Contact:

Alan Lada
(650) 606-7911
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EVERLAST-B Interim Data

ORKA-001 Phase 2b trial in psoriasis

October 26, 2026

Disclaimers

The information contained in this presentation has been prepared by Oruka Therapeutics, Inc. (the "Company") and pertains to the business and operations of the Company. The information: (a) is provided as of the date hereof, is subject to change without notice, and is based on publicly available information, internally developed data, and third-party sources; (b) does not purport to contain all information that may be necessary or desirable to fully and accurately evaluate an investment in the Company; (c) should not be considered a recommendation by the Company that any person make an investment in the Company; and (d) is for informational purposes only and does not constitute an offer to buy, sell, issue or subscribe for, or a solicitation of an offer to buy, sell, issue or subscribe for, any securities of the Company in any jurisdiction in which such offer, solicitation or sale would be unlawful. Any opinions or beliefs expressed in this presentation are based on certain assumptions and limitations and reflect the Company's current views only. This presentation should not be construed as legal, financial or tax advice, as individual circumstances may differ.

Forward-Looking Statements

Certain information set forth in this presentation contains "forward-looking statements" within the meaning of applicable United States securities legislation. Except for statements of historical fact, information contained herein may constitute forward-looking statements, including, but not limited to, statements regarding: expectations relating to the efficacy, durability of effect, dosing interval and safety of the Company's product candidates; plans for clinical trials and research and development programs, including the timing of clinical trials and data readouts; the expected sufficiency of the Company's capital resources; the Company's business strategy, objectives and goals; and management's assessment of future plans and operations. Forward-looking statements are based on current expectations, estimates, projections, assumptions and beliefs that may prove to be incorrect and are neither historical facts nor assurances of future performance. Such statements involve known and unknown risks, uncertainties and other factors that may cause actual results, performance or achievements to differ materially from those expressed or implied, including those described under "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements" in the Company's most recent filings with the U.S. Securities and Exchange Commission, including its Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and other filings. Additional risks and uncertainties relate to the biopharma industry, including those inherent in drug development. All forward-looking statements are qualified in their entirety by these cautionary statements. Although management believes such statements are reasonable when made, there can be no assurance that they will prove to be accurate. The Company undertakes no obligation to update forward-looking statements except as required by applicable securities laws. Readers are cautioned not to place undue reliance on forward-looking statements, which are made as of the date hereof and are presented solely to assist in understanding the Company's plans, objectives and goals.

Product Candidates

The Company is a clinical-stage biopharmaceutical company with no approved products. The product candidates described in this presentation are investigational and have not been approved for marketing by the U.S. Food and Drug Administration or any other regulatory authority. No representation is made as to the safety or effectiveness of these product candidates.

Industry Information

This presentation contains or references industry data based on independent publications, market research, surveys and other publicly available sources. Although the Company believes these sources to be generally reliable, such information is subject to interpretation and inherent limitations and cannot be verified with complete certainty. The Company has not independently verified such data and makes no representation or warranty as to its origin, validity, accuracy, completeness, currency or reliability.



Agenda

●	Introduction	Lawrence Klein, PhD Chief Executive Officer
●	ORKA-001 EVERLAST-B Phase 2b interim results	Joana Goncalves, MBChB Chief Medical Officer
●	Opportunities and next steps for Oruka	Lawrence Klein, PhD Chief Executive Officer
●	Analyst Q&A	Lawrence Klein, CEO Joana Goncalves, CMO Christopher Finch, SVP

Introduction

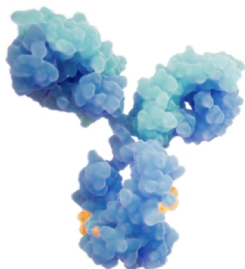
Lawrence Klein
CEO



Two co-lead programs aim to set a new standard in psoriasis

ORKA-001

Ultra-long-acting IL-23p19 mAb



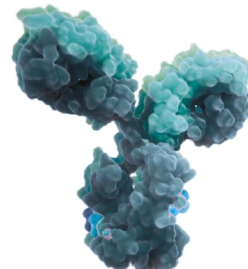
Efficacy profile potentially **best-in-indication**

Potential for **annual dosing** and **off-treatment remission**

Favorable safety consistent with IL-23p19 class

ORKA-002

Ultra-long-acting IL-17A/F mAb



First long-acting IL-17A/F in new **mega-blockbuster class**

Potential for **Q6M dosing** in PsO/PsA + **Q3M dosing** in HS

Pipeline-in-a-product expansion potential

Combinations with ORKA-001 and ORKA-002

ORKA-004 – Half-life extended TL1A mAb



Abbreviations: HS, hidradenitis suppurativa; PsA, psoriatic arthritis; PsO, psoriasis

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EVERLAST-B results confirm ORKA-001's remarkable profile



61% PASI 100 and 86% PASI 90 in ORKA-001 600 mg group at Week 16, consistent with EVERLAST-A	Two independent trials demonstrating +20pp PASI 100 and +10pp PASI 90 vs. leading IL-23s historically
Favorable safety profile similar to placebo	>100 patient-years of cumulative experience with ORKA-001, showing safety consistent with IL-23 class
Dose-ranging data supporting Phase 3 dose selection	Phase 3 start expected in 1H 2027



52-week EVERLAST-A data expected in December to support annual dosing potential



Notes: Cross-trial comparisons are for illustrative purposes only. Results are from separate clinical trials that may differ in design, patient population, and methods. No head-to-head trials have been conducted

EVERLAST-B

Interim Data

Joana Goncalves
CMO



EVERLAST-B is a global Phase 2b trial that builds on EVERLAST-A

36 experienced sites across North America & Europe

<30% site overlap with EVERLAST-A



Eligibility criteria mirrors prior anti-IL-23 trials, as in EVERLAST-A:

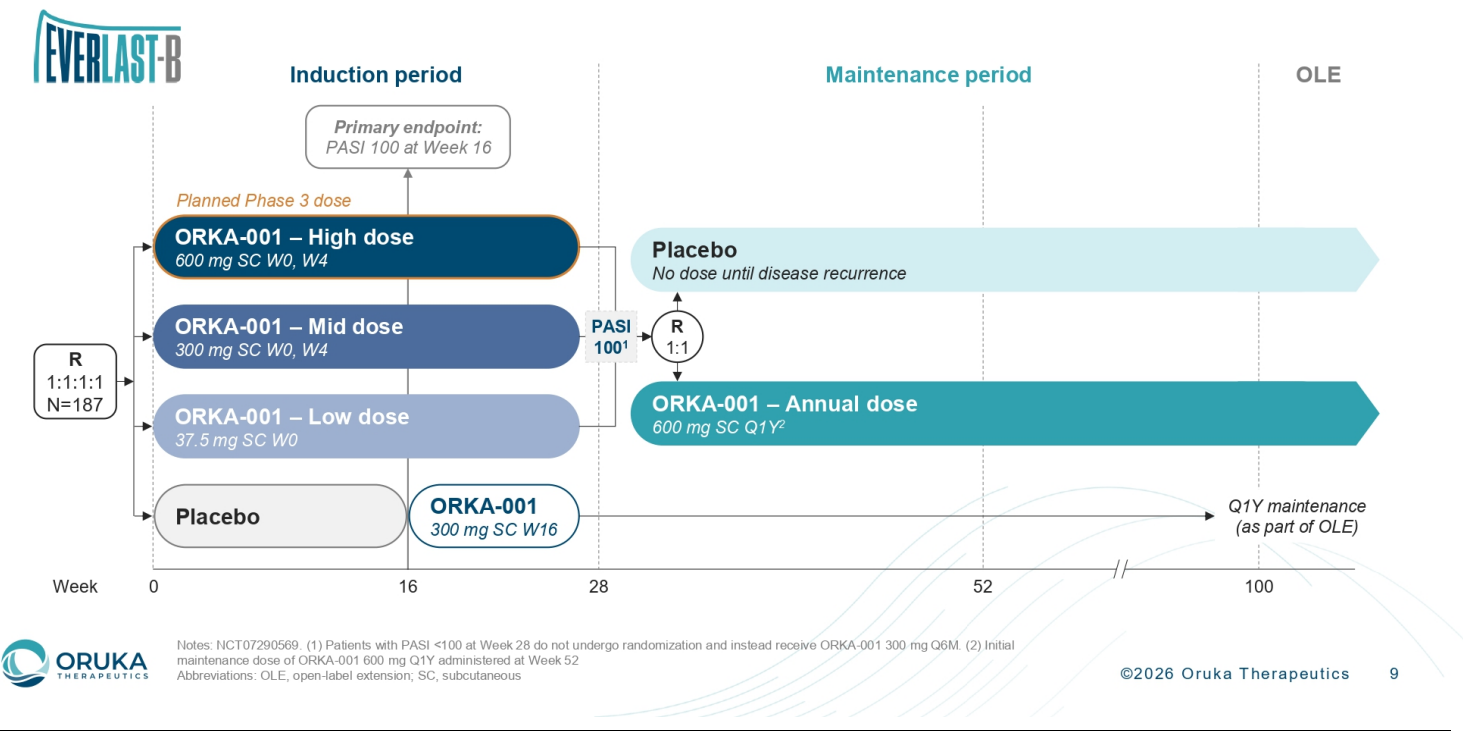
Adults ≥18 with moderate-to-severe chronic plaque psoriasis:

≥10% BSA	≥12 PASI	≥3 IGA
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Candidate for systemic therapy or phototherapy

No prior anti-IL-23p19 exposure, as in trials of risankizumab, guselkumab, and icotrokinra

EVERLAST-B is designed to enable dose selection for Phase 3

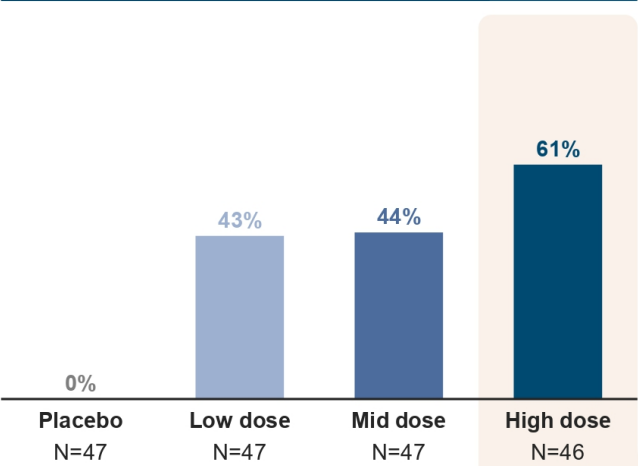


Baseline characteristics were balanced and comparable to prior trials in psoriasis

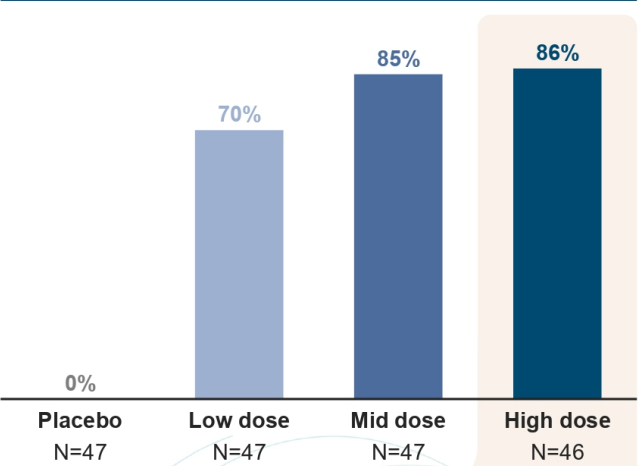
	Placebo N=47	Low dose N=47	Mid dose N=47	High dose N=46	EVERLAST-A N=63
Age, mean (SD)	42 (12)	43 (11)	45 (15)	46 (16)	45 (15)
Sex (female), %	15%	45%	36%	26%	29%
Race, %					
White	83%	77%	81%	78%	76%
Asian	9%	9%	6%	7%	13%
Other or not reported	9%	15%	13%	15%	11%
Weight (kg), mean (SD)	91 (24)	91 (21)	86 (21)	93 (25)	84 (16)
BMI, mean (SD)	30 (7)	32 (7)	30 (6)	31 (6)	28 (4)
Disease duration (years), mean (SD)	16 (11)	14 (9)	21 (13)	16 (12)	15 (12)
BSA (%), mean (SD)	21% (11)	21% (15)	19% (11)	20% (13)	21% (12)
PASI, mean (SD)	18 (6)	18 (6)	17 (5)	18 (6)	18 (7)
IGA, %					
3	77%	77%	87%	78%	71%
4	23%	23%	13%	22%	29%
Prior biologic use, %	21%	23%	21%	22%	14%

ORKA-001 high dose demonstrated the highest skin clearance

PASI 100 at Week 16 (primary endpoint)¹



PASI 90 at Week 16



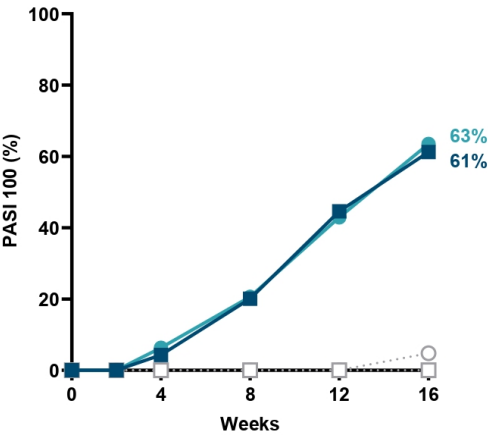
High dose (600 mg) planned for Phase 3 based on highest efficacy



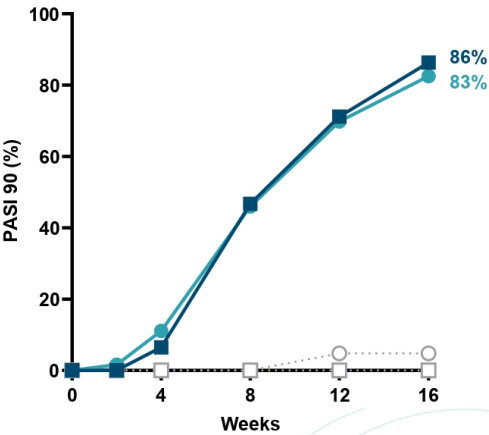
Notes: (1) p<0.0001 for all doses vs. placebo. Identical IGA 0 results

Highly consistent response trajectories observed in each trial

PASI 100



PASI 90



EVERLAST-B

600 mg ORKA-001
N=46

Placebo
N=47

EVERLAST-A

600 mg ORKA-001
N=63

Placebo
N=21

Similar performance across additional endpoints in EVERLAST-B vs. -A:
IGA 0/1: 86% vs. 84% | PASI 75: 95% vs. 94%

Favorable safety profile consistent with the IL-23p19 class

Planned Phase 3 dose					
Week 0-16	Placebo N=47	Low dose N=47	Mid dose N=47	High dose N=46	All ORKA-001 N=140
Patients reporting ≥1 TEAE, n (%)	20 (43%)	22 (47%)	28 (60%)	18 (39%)	68 (49%)
Patients reporting ≥1 serious TEAE, n (%)	2 (4%)	1 (2%)	2 (4%)	-	3 (2%)
Patients reporting ≥1 severe TEAE, n (%)	2 (4%)	1 (2%)	2 (4%)	-	3 (2%)
Discontinuation due to TEAE, n (%)	1 (2%)	1 (2%)	1 (2%)	-	2 (1%)
Most frequent TEAEs ¹ , n (%)					
Upper respiratory tract infection ²	4 (9%)	5 (11%)	9 (19%)	6 (13%)	20 (14%)
Headache ³	1 (2%)	2 (4%)	3 (6%)	3 (7%)	8 (6%)
Injection site reactions, n (%)	1 (2%)	-	-	-	-



Abbreviations: TEAE, treatment-emergent adverse event

Notes: No serious or severe TEAEs were considered related to treatment. These TEAEs were kidney stones, miscarriage, psoriasis, substance-induced psychotic disorder, and syncope following a blood draw and jaw fracture. (1) TEAEs occurring in ≥5% of participants treated with ORKA-001. (2) Preferred Terms (PT) of upper respiratory tract infection, influenza, nasal congestion, nasopharyngitis, pharyngitis, rhinitis, and sinusitis. (3) PTs of headache and migraine

Advancing rapidly towards Phase 3 and additional readouts



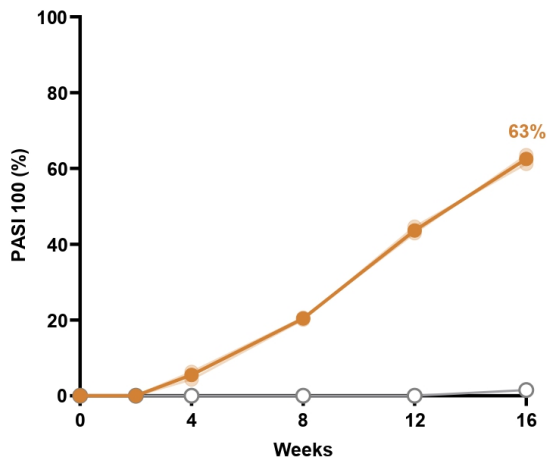
Opportunities and next steps

Lawrence Klein
CEO

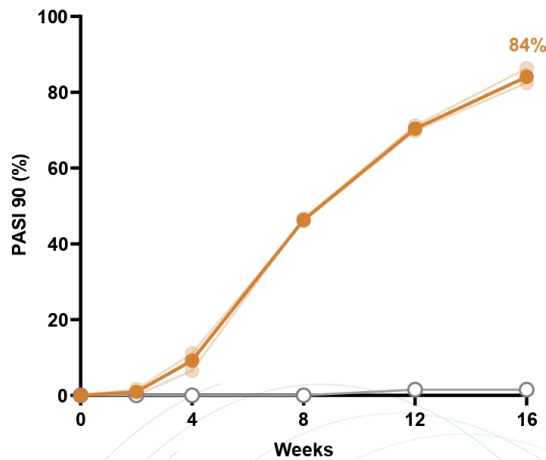


ORKA-001 delivered exceptional efficacy across EVERLAST-A & B

PASI 100 (pooled)



PASI 90 (pooled)



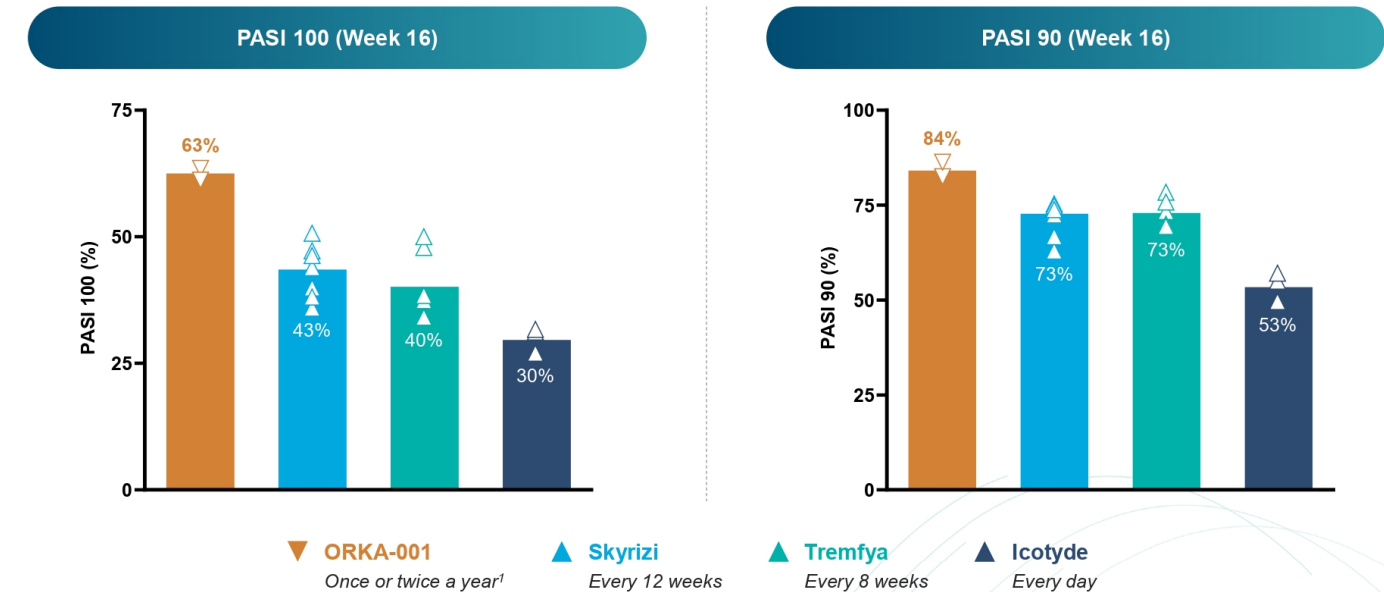
600 mg ORKA-001 (N=109)

Placebo (N=68)



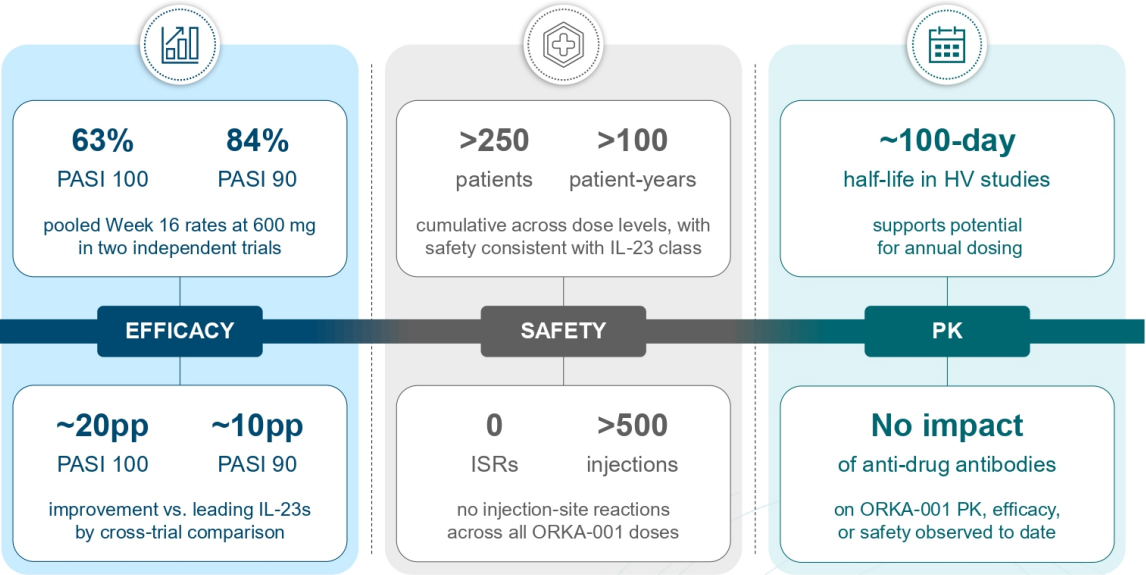
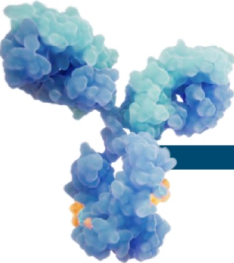
Notes: Solid lines show weighted average response across EVERLAST-A and -B. Transparent lines show performance of ORKA-001 in each individual trial

Leading efficacy potential in an ultra-long-acting IL-23 inhibitor



Notes: Bars show weighted average response across all company-sponsored trials in moderate-to-severe psoriasis with U.S. sites using the approved dosing for each drug. Icons show performance of each individual trial. (1) Anticipated dosing. Cross-trial comparisons are for illustrative purposes only. Results are from separate clinical trials that may differ in design, patient population, and methods. No head-to-head trials have been conducted. Sources: UlimMa-1/2 (N=304 and 294), IMMHance (N=407), IMMvent (N=301), IMMerge (N=164), NCT03875482 (N=105), NCT03875508 (N=108), VOYAGE 1/2 (N=329 and 496), ECLIPSE (N=534), IXORA-R (N=507), ORION (N=62), ICONIC-LEAD (N=456), ICONIC-ADVANCE-1/2 (N=311 and 322).

Growing body of evidence for ORKA-001 as a step change in PsO

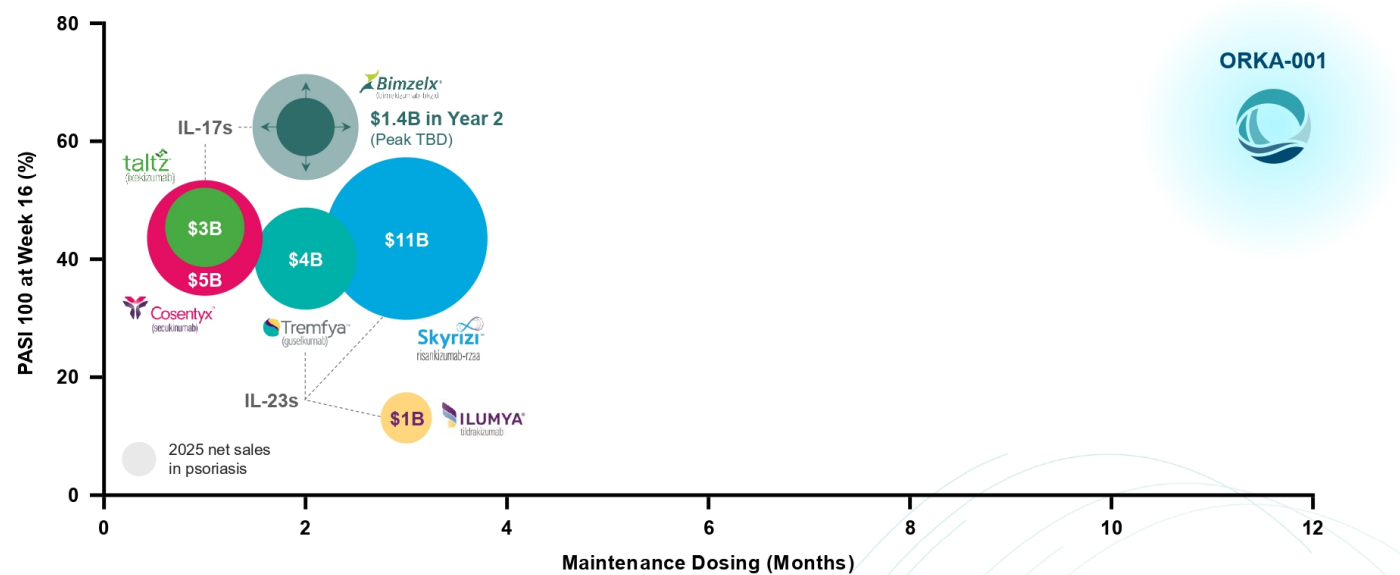


Phase 3 initiation anticipated in 1H 2027



Notes: Cross-trial comparisons are for illustrative purposes only. Results are from separate clinical trials that may differ in design, patient population, and methods. No head-to-head trials have been conducted

ORKA-001 could stand apart in a space that has created multiple \$5-10B+ products



Notes & Sources: Evaluate Pharma global net sales estimates, excluding psoriatic arthritis. Weighted average response from all company-sponsored trials in moderate-to-severe psoriasis with U.S. sites using approved dosing for bimekizumab (N=4), nsankizumab (N=7), guselkumab (N=5), secukinumab (N=7), ixekizumab (N=3), and tildrakizumab (N=2, Week 12 data shown as Week 16 PASI 100 not reported) (sources on file)

Well-funded through multiple anticipated upcoming milestones



Strong cash position (\$1B+)¹ expected to provide runway through ORKA-001 BLA filing



Notes: (1) As of June 30, 2026

