January 12, 2026

Skye Provides 2026 Corporate Outlook

- *CBeyond™ Phase 2a 26-week extension data update and interim results expected Q1 2026.*
- *CBeyond Phase 2a Data Monitoring Committee (DMC) meeting on December 14, 2025, continued to demonstrate favorable safety profile.*
- *CBeyond Phase 2a topline results to 52 weeks including 13-week off-therapy follow-up period expected in Q3 2026.*
- *Phase 2b (CBeyond 2) plan to be finalized in Q1; trial launch targeted for Q3 2026.*

SAN DIEGO, Jan. 12, 2026 (GLOBE NEWSWIRE) -- Skye Bioscience, Inc. (Nasdaq: SKYE) ("Skye") a clinical-stage biotechnology company focused on unlocking new therapeutic pathways for obesity and other metabolic health disorders, today provided its 2026 corporate outlook outlining planned clinical, manufacturing, and corporate milestones to advance nimacimab, Skye's peripherally restricted CB1-inhibiting antibody.

"In 2025 we generated our Phase 2a clinical data, deepened our understanding of nimacimab's exposure-response dynamics, and built the technical foundation required to test higher doses and prepare the framework for a potential subsequent Phase 2 trial with broader clinical endpoints," said Punit Dhillon, President & Chief Executive Officer. "In 2026, our focus and goals are straightforward: deliver additional clinical readouts from our CBeyond extension study, assess and select higher doses of nimacimab, and launch a Phase 2b study designed to evaluate multiple doses of nimacimab as a monotherapy and in combination with an incretin therapy."

"We believe emerging data across the obesity treatment landscape underscore the need for modalities complementary to incretin–based therapies," added Mr. Dhillon. "We believe peripheral CB1 inhibition offers a distinctive opportunity to help achieve incremental weight loss, improve treatment tolerability and sustainability, enhance post-treatment durability, as well as offer additional metabolic and inflammatory benefits."

2025 Foundation Supporting 2026 Execution

CBeyond Phase 2a delivered clinically relevant signals and and new insight to further guide development

- **Additive weight loss in combination with semaglutide**. Clinically meaningful additional weight loss of nimacimab and semaglutide versus semaglutide alone, with no plateau observed at 26 weeks, highlighted for the first time the complementary positive effect of a peripheral CB1 inhibitor with an incretin therapeutic.
- **Additive reduction in waist circumference and superior lean to fat mass ratio**was also observed with the addition of nimacimab to semaglutide.
- CBeyond provided **insight into dose-response**, informing the next stage of dose

selection and study design.

- **Positive safety and tolerability**. Nimacimab alone demonstrated a favorable safety profile with placebo-like tolerability. In combination with semaglutide, there was no increase in gastrointestinal adverse events. Importantly, there was no difference in neuropsychiatric adverse events reported resulting from treatment with nimacimab compared to placebo or from the combination of nimacimab and semaglutide compared to semaglutide alone.
- See Phase 2a 26-week data news release for full details along with investor presentation and Spotlight page for detailed charts and explanations.

Preclinical research validates broad potential utility of nimacimab

- **Significant weight loss** in DIO mouse models as a monotherapy as well as in combination with both an active or suboptimal dose of tirzepatide.
- **Significantly less weight rebound** post-treatment compared to incretin drugs and in cohorts administered nimacimab following treatment with incretin drugs.
- **Productive modulation of gut and adipose hormones** integral to metabolic and anti-inflammatory processes.
- **Foundational evidence for efficacy of** antibody-based peripherally-restricted CB1 inhibition and the role nimacimab plays to complement GLP-1/incretin-based mechanisms.
- Results can be reviewed in Skye's investor presentation and are explained in "primer" videos on Skye's Spotlight page.

Operational groundwork for higher-dose delivery and scalability

- **CMC and clinical supply readiness.** Advanced manufacturing scale-up and CMC execution, producing nimacimab drug supply for planned follow-on studies and de-risking near-term clinical execution.
- **Higher dosing with enhanced concentration and injection volume**. Planning for optimal high-dose drug administration, through 2025 Skye initiated collaborations focused on this goal:
    - **May:** agreement with Arecor Therapeutics plc (AIM: AREC) to develop a higher concentration formulation of nimacimab using Arecor's proprietary formulation technology platform, Arestat™.
    - **December:** licensed Halozyme Therapeutics' ENHANZE® drug delivery technology to develop and potentially commercialize a subcutaneous formulation of nimacimab that may facilitate larger injection volumes.

Looking Ahead to 2026: Key Objectives and Expected Clinical Milestones

Clinical development: generate longer-duration data and establish the right dose

Skye's 2026 clinical program goals are designed to (i) evaluate multiple higher doses of nimacimab, and (ii) initiate a Phase 2b study that supports combination development.

Planned clinical milestones include:

- CBeyond™ Phase 2a 26-week extension data update and interim results expected in Q1 2026.
- CBeyond Phase 2a topline results to 52 weeks including 13-week off-therapy follow-up period expected in Q3 2026.
- Phase 2b (CBeyond 2) plan will be finalized and aligned with regulators, including completion of a Type C meeting in Q1 2026, with initiation of the adaptive design Phase 2b clinical trial expected in Q3 2026.

About Nimacimab

Nimacimab is a potential first-in-class, peripherally-restricted monoclonal antibody inhibitor of the CB1 receptor. Unlike previous CB1-targeting drugs, nimacimab is designed to avoid central nervous system penetration, potentially limiting neuropsychiatric side effects seen with small-molecule antagonists. As a non-incretin, non-peptide agent, nimacimab acts independently of the GLP-1 pathway and has also demonstrated additive or complementary effects in combination with incretin-based therapies in preclinical and clinical studies.

About Skye Bioscience

Skye is focused on unlocking new therapeutic pathways for metabolic health through the development of next-generation molecules that modulate G-protein coupled receptors. Skye's strategy leverages biologic targets with substantial human proof of mechanism for the development of first-in-class therapeutics with clinical and commercial differentiation. Skye is conducting a Phase 2a clinical trial (ClinicalTrials.gov: NCT06577090) in obesity for nimacimab, a negative allosteric modulating antibody that peripherally inhibits CB1. This study is also assessing the combination of nimacimab and a GLP-1R agonist (Wegovy®). For more information, please visit: www.skyebioscience.com. Connect with us on X and LinkedIn.

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FORWARD LOOKING STATEMENTS

This press release includes “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release other than statements of historical fact should be considered forward-looking statements, including, without limitation, statements relating to: Skye's future plans and prospects, planned clinical milestones; plans to advance nimacimab into the next stage of development to optimize dosing; future clinical development of nimacimab, including the initiation and design of any future clinical trials; the expected timing for reporting data from the Phase 2a extension study; the potential market opportunities; any expectations regarding the efficacy and therapeutic potential of nimacimab; the potential for nimacimab to be a first-in-class drug. When used herein, words including “anticipate,” “believe,” “can,” “continue,” “could,” “designed,” “estimate,” “expect,” “forecast,” “goal,” “intend,” “may,” “might,” “plan,” “planning,” “possible,” “potential,” “predict,” “project,” “should,” “target,” “will,” “would” and similar expressions are intended to identify forward-looking statements, though not all forward-looking statements use these words or expressions. All forward-looking statements are based upon the Company’s current expectations and various assumptions. The Company believes there is a reasonable basis for its expectations and beliefs, but they are inherently uncertain. The Company may not realize its expectations, and its beliefs may not prove correct. Actual results could differ materially from those described or implied by such forward-looking statements as a result of various important risks and uncertainties, including, without limitation, the initiation and design of any future clinical trials will be impacted by the Company’s capital resources, the Company’s ability to obtain additional sources of capital needed to run an additional Phase 2 clinical trial, program considerations and potentially other factors outside the Company’s control; the Company’s dependence on third parties in connection with product manufacturing; research and preclinical and clinical testing; the Company’s ability to advance, obtain regulatory approval of and ultimately commercialize nimacimab, competitive products or approaches limiting the commercial value of nimacimab; the timing and results of preclinical and clinical trials; the Company’s ability to fund development activities and achieve development goals; the impact of any global pandemics, inflation, supply chain issues, government shutdowns, high interest rates, adverse regulatory changes; the Company’s ability to protect its intellectual property; risks associated with the Company’s common stock and the other important factors discussed under the caption “Risk Factors” in the Company’s filings with the Securities and Exchange Commission, including in its Annual Report on Form 10-K for the year ended December 31, 2024, which are accessible on the SEC’s website at www.sec.gov and the Investors section of the Company’s website. Any such forward-looking statements represent management’s estimates as of the date of this press release. While the Company may elect to update such forward-looking statements at some point in the future, except as required by law, it disclaims any obligation to do so, even if subsequent events cause the Company’s views to change. These forward-looking statements should not be relied upon as representing the Company’s views as of any date subsequent to the date of this press release.

Source: Skye Bioscience, Inc.