May 11, 2026

Skye Bioscience Reports First Quarter 2026 Financial Results and Business Update

- *CBeyond™ Expansion Study (Part C) initiated; Cohort Review Committee review scheduled for May 18, 2026, to evaluate available safety data and potential progression to Cohort 2*
- *Engaged Lilly Catalyze360 to provide strategic guidance on nimacimab TPP and Phase 2b trial design*

SAN DIEGO, May 11, 2026 (GLOBE NEWSWIRE) -- Skye Bioscience, Inc. (Nasdaq: SKYE) (“Skye” or the “Company”), a clinical stage biotechnology company developing next-generation molecules that modulate G-protein-coupled receptors to treat obesity, overweight, and related conditions, today reported financial results for the first quarter ended March 31, 2026, along with recent business updates and anticipated milestones.

“Since our March update, execution has focused on turning CBeyond into a Phase 2b-ready development program,” said Punit Dhillon, President & CEO of Skye. “We have now initiated enrollment of Cohort 1 of the CBeyond Expansion Study, executed the compatibility and in-use study with ENHANZE to support a practical high-volume subcutaneous approach, and engaged external development advisors to help pressure-test our target product profile, dose-selection rationale and Phase 2b trial design. Our objective in 2026 remains focused on defining the dose and exposure that can support a larger Phase 2b study evaluating nimacimab as a complementary add-on approach for GLP-1-experienced patients.”

Business and Clinical Highlights

CBeyond™ Expansion Study (Part C)

- Cohort 1 is designed to evaluate nimacimab 400 mg IV (equivalent to ~700 mg SC) once weekly versus matched placebo, randomized 3:1, over a 16-week treatment period followed by 12 weeks of follow-up.
- The Cohort Review Committee (CRC) is scheduled to meet on May 18, 2026 to review available Cohort 1 safety data and determine whether safe-to-proceed criteria have been met to initiate enrollment in Cohort 2.
- Cohort 2 is designed to evaluate nimacimab 600 mg IV (equivalent to ~1000 mg SC) once weekly versus matched placebo, randomized 3:1, over the same treatment and follow-up period.
- Skye continues to expect topline clinical data from the CBeyond Expansion Study in Q4 2026. The study is designed to generate higher-exposure human safety and pharmacokinetic data to inform dose selection for a planned Phase 2b study.

Q1 Accomplishments

- Skye has completed all previously announced clinical milestones for Q1: reported CBeyond interim extension data, received FDA Type C meeting minutes, launched the CBeyond Expansion Study (Part C), and completed a compatibility and in-use stability study with ENHANZE.
- The Company remains on track to complete the Q2 2026 catalyst set, including initiation of Cohort 2 enrollment, pending receipt of the CRC's determination that safe-to-proceed criteria have been met, completion of enrollment across Cohorts 1 and 2, presentation or disclosure of additional preclinical bioconjugation data, and completion of feasibility work for the high-concentration nimacimab program.

Clinical Data Foundation Supporting the Current Development Strategy

- In previously reported CBeyond data, nimacimab plus semaglutide demonstrated an approximately 3% incremental weight-loss benefit versus semaglutide alone at 26 weeks, with statistically significant improvements in waist circumference and lean-to-fat mass ratio.
- In the previously reported interim 52-week combination update, participants receiving nimacimab 200 mg plus semaglutide 2.4 mg achieved 22.3% mean weight loss, with no plateau observed at the time of analysis.
- At the tested dose, nimacimab demonstrated a favorable tolerability profile, with no nimacimab-associated neuropsychiatric safety signal observed and no additive gastrointestinal adverse-event burden when combined with semaglutide.
- During off-therapy follow-up, the nimacimab plus semaglutide cohort demonstrated lower weight regain than the semaglutide-alone cohort, and available body-composition data suggested maintenance of fat-mass loss and improvement in lean-to-fat mass ratio during follow-up.
- Skye believes these findings support development of nimacimab as complementary to, rather than competitive with, incretin therapies, particularly for GLP-1-experienced patients who plateau, require additional weight loss, are titration-limited, or need more durable metabolic control.

Phase 2b Planning

- Skye has received written FDA Type C meeting minutes and is incorporating feedback into ongoing Phase 2b planning, including dose, duration, endpoints, inclusion/exclusion criteria and a defined indication and patient population for nimacimab as an add-on therapy to incretins.
- Skye has engaged Lilly Catalyze360 in a development consulting engagement to provide written feedback on the nimacimab target product profile, and Phase 2b trial architecture.
- This engagement is a development advisory engagement and does not constitute a commitment regarding any future transaction, therapeutic interest, exclusivity or corporate business development process.

CMC and Drug Delivery Strategy

- Skye has executed the compatibility and in-use study with Halozyme's ENHANZE® (rHuPH20) technology to support a planned site-based "mix-and-deliver" approach for high-volume subcutaneous administration of nimacimab in future clinical development.
- Co-formulation with ENHANZE is intended to support practical subcutaneous delivery

of higher nimacimab doses.
- Skye continues feasibility work on a high-concentration nimacimab formulation, with the objective of reducing injection volume and supporting patient-friendly subcutaneous administration across potential dose levels.
- Skye continues to evaluate manufacturing process improvements, supply-chain options and cost-of-goods levers to support late-stage development and potential commercial scalability if nimacimab is approved.

Upcoming Anticipated Milestones

- Q2 2026: Cohort Review Committee review of available Cohort 1 safety data and potential initiation of Cohort 2 enrollment.
- Q2 2026: Complete enrollment across CBeyond Expansion Study Cohorts 1 and 2.
- Q2 2026: Complete feasibility work for the high-concentration nimacimab formulation program.
- Q4 2026: Report topline clinical data from the CBeyond Expansion Study.
- Q4 2026: Finalize planned Phase 2b study design, including dose-selection rationale, protocol architecture and operational readiness plan.

First Quarter 2026 Financial Results:

Balance Sheet and Cash Flow Highlights

- Cash, cash equivalents and short-term investments totaled $17.1 million as of March 31, 2026. The Company expects its current capital to fund projected operations and key clinical milestones through the fourth quarter of 2026, including completion of its Phase 2a extension study for nimacimab and initial manufacturing to enable the anticipated Phase 2b clinical study, but excluding the anticipated clinical cost of a proposed Phase 2b clinical study and additional anticipated drug manufacturing costs to supply any such Phase 2b study.

Operating Results

- **R&D Expenses**
  Research and development (R&D) expenses for the three months ended March 31, 2026, were $7.9 million, as compared to $7.2 million for the same period in 2025. The increase was primarily due to contract manufacturing, clinical trial costs associated with our clinical study for nimacimab, discovery research and development expenses, salaries and stock-based compensation expense, and consulting advisory and professional fees.

- **G&A Expenses**
  General and administrative (G&A) expenses for the three months ended March 31, 2026, were $4.7 million, as compared to $4.6 million for the same period in 2025. The increase was primarily related to increased legal fees, partially offset by decreases in investor relations, marketing and communications expenses, salaries, benefits and other direct employee related costs, and consulting, advisory and professional fees.

- **Net Loss**
  Net loss for the three months ended March 31, 2026, totaled $12.5 million, with non-

cash stock-based compensation expense of $1.5 million, compared to $11.1 million for the same period in 2025, with non-cash stock-based compensation expense of $2.2 million.

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.

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: nimacimab’s potential as a combination or maintenance therapy by supplement GLP-1 therapies; future clinical development of nimacimab, including the initiation and design of any future clinical trials; expectations regarding the CRC’s review of available Cohort 1 safety data to determine whether safe-to-proceed criteria have been met to initiate enrollment in Cohort 2; the outcome of Skye's evaluation of its manufacturing process improvements, supply-chain options and cost of goods levers; the expected timing for reporting data from the Phase 2a extension study; and the Company’s cash runway. 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, program considerations and potentially other factors outside the Company’s control; the potential for additional weight loss after 26 weeks may not ultimately be observed; there is no guarantee that higher dosing of nimacimab will achieve increased efficacy, and likewise it is possible that higher dosing will produce adversely different safety and tolerability results than those observed to date; 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, 2025 and Quarterly Report on Form 10-Q for the quarter ended March 31, 2026, 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.

	For the Three Months Ended March 31,	
	2026	**2025**
Operating expenses		
Research and development	$ 7,935,680	$ 7,197,257
General and administrative	4,738,686	4,562,305
Total operating expenses	12,674,366	11,759,562
Operating loss	(12,674,366)	(11,759,562)
Other (income) expense		
Interest expense	2,199	1,452
Interest and other income, net	(169,615)	(619,054)
Other (income) expense	2,411	(40,641)
Total other (income) expense, net	(165,005)	(658,243)
Loss before income taxes	(12,509,361)	(11,101,319)
Provision for income taxes	—	2,000
Net loss	$(12,509,361)	$(11,103,319)
Loss per common share:		
Basic	$ (0.32)	$ (0.28)
Diluted	$ (0.32)	$ (0.28)
Weighted average shares of common stock outstanding used to compute loss per share:		
Basic	39,681,465	39,651,888
Diluted	39,681,465	39,651,888

	March 31, 2026 (Unaudited)	December 31, 2025
ASSETS		
Current assets		
Cash and cash equivalents	$ 8,149,015	$ 5,882,498
Short-term investments	8,959,614	19,854,723
Prepaid expenses	1,223,534	504,890
Other current assets	234,806	852,036
Total current assets	18,566,969	27,094,147
Property and equipment, net	756,077	898,930
Operating lease right-of-use asset	57,781	266,646
Other assets	35,909	53,910
Total assets	$ 19,416,736	$ 28,313,633
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 3,936,948	$ 2,033,431
Accrued payroll liabilities	234,392	1,269,474
Other current liabilities	3,347,515	2,643,840
Estimate for accrued legal contingencies and related expenses	2,574,759	2,069,067
Insurance premium loan payable	250,338	—
Operating lease liability, current portion	60,980	189,647
Total current liabilities	10,404,932	8,205,459
Non-current liabilities		
Operating lease liability, net of current portion	—	83,999
Total liabilities	10,404,932	8,289,458
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.001 par value; 200,000 shares authorized at March 31, 2026 and December 31, 2025; no shares issued and outstanding at March 31, 2026 and December 31, 2025	—	—

Common stock, $0.001 par value; 100,000,000 shares authorized at March 31, 2026 and December 31, 2025; 35,126,884 and 33,378,139 shares issued and outstanding at March 31, 2026 and December 31, 2025, respectively	35,128	33,379
Additional paid-in-capital	208,360,523	206,865,282
Accumulated deficit	(199,383,847)	(186,874,486)
Total stockholders' equity	9,011,804	20,024,175
Total liabilities and stockholders' equity	**$ 19,416,736**	**$ 28,313,633**

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