



Kodiak Sciences Announces Recent Business Highlights and First Quarter 2025 Financial Results

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PALO ALTO, Calif., May 14, 2025 /PRNewswire/ -- Kodiak Sciences Inc. (Nasdaq: KOD), today reported recent business highlights and financial results for the first quarter ended March 31, 2025.

"In the first quarter of 2025, we maintained a strong focus on execution. We look forward to sharing our progress at an Investor R&D Update scheduled for July 16, 2025 at 1:00pm Eastern Time. We aim to demonstrate that our vision for Kodiak 2.0 as a precommercial stage retina focused biotech company with a maturing portfolio of three promising Phase 3 assets on track for topline data in 2026 is well-supported by our science and our progress on execution," said Victor Perloth, M.D., Chairman and Chief Executive Officer of Kodiak Sciences.

Recent Business Highlights and Upcoming Catalysts

We plan to host an Investor R&D Update on July 16, 2025 at 1:00pm ET. The update will feature scientific, clinical and commercial perspectives across the Kodiak pipeline. The agenda is expected to include the following:

- **Tarcocimab:**
 - Phase 3 GLOW2 diabetic retinopathy study – expected timeline to topline data
 - Phase 3 DAYBREAK wet AMD study – update on enrollment completion and expected timeline to topline data
 - Update on Biologics License Application (BLA) facing activities
- **KSI-501:**
 - Phase 3 DAYBREAK wet AMD study – update on enrollment completion and expected timeline to topline data
 - Discussion on next clinical steps for KSI-501
- **KSI-101:**
 - New APEX Phase 1b multiple dose clinical trial data in patients with Diabetic Macular Edema (DME)
 - New APEX Phase 1b multiple dose clinical trial data in patients with Macular Edema Secondary to Inflammation (MESI)
 - Discussion on clinical and regulatory plan for KSI-101 in MESI with projected timeline to topline data
 - Phase 3 MESI study design & initiation of Phase 3 trials
 - Discussion on commercial opportunity for KSI-101

First Quarter 2025 Financial Results

Cash Position

Kodiak ended the first quarter of 2025 with \$138.9 million of cash and cash equivalents. We believe that our current cash will support our current and planned operations into 2026.

Net Loss

The net loss for the first quarter of 2025 was \$57.5 million, or \$1.09 per share on both a basic and diluted basis, as compared to a net loss of \$43.0 million, or \$0.82 per share on both a basic and diluted basis, for the first quarter of 2024. The net loss for the quarter ended March 31, 2025 included non-cash stock-based compensation of \$15.9 million, as compared to \$18.4 million for the quarter ended March 31, 2024.

R&D Expenses

Research and development ("R&D") expenses were \$43.6 million for the quarter ended March 31, 2025, as compared to \$29.9 million for the quarter ended March 31, 2024. The R&D expenses for the first quarter of 2025 included non-cash stock-based compensation of \$7.9 million, as compared to \$8.7 million for the first quarter of 2024. The increase in R&D expenses in the first quarter of 2025 was primarily driven by increased clinical activities related to our active GLOW2, DAYBREAK, and APEX studies, as well as increased manufacturing activities.

G&A Expenses

General and administrative ("G&A") expenses were \$15.4 million for the quarter ended March 31, 2025, as compared to \$16.1 million for the quarter ended March 31, 2024. The G&A expenses for the first quarter of 2025 included non-cash stock-based compensation of \$8.0 million, as compared to \$9.7 million for the first quarter of 2024.

About Tarcocimab

Tarcocimab is an investigational anti-VEGF therapy built on Kodiak's proprietary Antibody Biopolymer Conjugate ("ABC") Platform and is designed to maintain potent and effective drug levels in ocular tissues for longer than existing available agents. Tarcocimab is being developed as a mainstay intravitreal biologic monotherapy that provides high immediacy, driven by the enhanced formulation, and high durability, driven by the ABC[®] platform and our science of durability, with the ultimate objective of providing, once approved, a flexible 1-month through 6-month label for all patients with retinal vascular disease (treatment-naïve, treatment-experienced, mild patients, severe patients).

To date, tarcocimab has completed three successful Phase 3 pivotal clinical studies: the Phase 3 GLOW1 study in diabetic retinopathy ("DR"), the Phase 3 BEACON study in retinal vein occlusion ("RVO") and the Phase 3 DAYLIGHT study in wet AMD. In the GLOW1 study, tarcocimab

successfully treated DR patients and prevented disease progression with 100% of patients on extended 6-month dosing. In the BEACON study, in the first 6 months tarcocimab-treated patients were dosed on every 8-week interval (as opposed to every 4-week interval for aflibercept) and in the second 6 months nearly half of tarcocimab patients did not require any treatment while achieving similar vision and anatomical outcomes as the aflibercept group at one year.

Tarcocimab is currently being studied in two Phase 3 clinical trials, the GLOW2 study in DR and the DAYBREAK study in wet AMD. GLOW2 has completed enrollment and DAYBREAK is actively enrolling. The GLOW2 study design mirrors that of our successful GLOW1 study in DR, with the advantage of a third monthly loading dose (baseline, Week 4, Week 8) to provide dosing flexibility to providers. All patients randomized to investigational therapy will receive tarcocimab on extended, 6-month dosing.

Both GLOW2 and DAYBREAK use tarcocimab's enhanced 50 mg/mL formulation containing both conjugated and unconjugated antibody that is intended to balance immediacy and durability.

About GLOW1 (complete) and GLOW2 (ongoing):

The Phase 3 GLOW1 demonstrated that with extended 6-month dosing in every patient, tarcocimab can achieve strong efficacy both in treating existing disease (primary endpoint) and preventing vision threatening complications and disease progression (key secondary endpoint). In GLOW1, tarcocimab met its primary endpoint of the proportion of patients with at least a 2-step improvement on the Diabetic Retinopathy Severity Scale ("DRSS") score with 41.1% of tarcocimab-treated patients demonstrating at least a 2-step improvement vs. 1.4% of patients in the sham group, a 29-fold increased response rate ratio (p-value less than 0.0001). Tarcocimab also met all key secondary endpoints, including greater reductions in the proportion of patients developing sight-threatening complications (such as diabetic macular edema and proliferative diabetic retinopathy), versus sham, demonstrating an 89% decreased risk, achieving 21.0% versus 2.3% (p-value less than 0.0001). Tarcocimab also showed a 95% risk reduction in the development of DME, versus sham, from 13.7% on sham versus 0.7% on tarcocimab.

The Phase 3 GLOW2 study is a prospective, randomized, double-masked, multi-center pivotal superiority study designed to evaluate the efficacy and safety of tarcocimab tedromer in treatment-naïve patients with DR. Patients are randomized 1:1 and receive either sham injections or tarcocimab via intravitreal injection at baseline, Week 4, Week 8, Week 20 and Week 44. The primary endpoint is the proportion of eyes improving ≥ 2 steps on Diabetic Retinopathy Severity Scale ("DRSS") from baseline at Week 48. Additional outcome measures include the proportion of eyes developing a sight threatening complication of diabetic retinopathy and the proportion of eyes improving ≥ 3 steps on DRSS from baseline at Week 48. Additional information about GLOW2 (also called Study KS301P108) can be found on www.clinicaltrials.gov under Trial Identifier NCT06270836 (<https://clinicaltrials.gov/show/NCT06270836>).

About DAYBREAK and tarcocimab:

The Phase 3 DAYBREAK study is a non-inferiority study evaluating parallel investigational arms of tarcocimab and KSI-501 against active comparator aflibercept. The DAYBREAK study incorporates learnings from prior pivotal trials of tarcocimab and was designed to maximize the probability of meeting the primary endpoint of non-inferiority in visual acuity gains. Patients randomized to tarcocimab will receive individualized dosing every 4 to 24 weeks on an as needed basis following four monthly loading doses. Patients randomized to aflibercept will be dosed per label. The individualized dosing of tarcocimab is determined by a treat-to-dryness proactive approach using presence of retinal fluid as a disease activity marker, which resembles retina specialists' practice and optimizes each patient's treatment instead of a combination of central subfield thickness ("CST") and vision loss. The objectives for tarcocimab in DAYBREAK are to assess its 6-month durability potential, strengthen its competitive position in wet AMD and bolster the possible regulatory application package for the program. In particular, we hope DAYBREAK will allow tarcocimab to showcase its potential to be a mainstay biologic for VEGF-driven retinal vascular diseases that has both strong efficacy/immediacy driven by its enhanced formulation, and strong durability driven by its ABC[®] design and science of durability.

About KSI-501

KSI-501 is an investigational anti-IL-6, VEGF-trap bispecific therapy built on the ABC platform and is being developed for high prevalence retinal vascular diseases to address the leading unmet needs of extended durability and targeting disease biology beyond VEGF for differentiated efficacy. KSI-501 is designed to provide high immediacy/efficacy, driven by the enhanced formulation, and high durability, driven by the ABC[®] platform and our science of durability.

In preclinical models, KSI-501 was shown to be a potent inhibitor of VEGF and IL-6 and, further, was shown to normalize the blood retinal barrier, opening up the possibility that KSI-501 may be a disease-modifying therapy for retinal vascular diseases. Furthermore, higher intraocular levels of IL-6 correlated with poorer BCVA outcomes over time in wet AMD patients treated with anti-VEGF monotherapy, which suggests that IL-6 inhibition in combination with anti-VEGF therapy could lead to improved outcomes.

A completed Phase 1 multiple ascending dose study demonstrated that repeated monthly dosing of KSI-501 was well tolerated and achieved clinically meaningful and sustained improvement in visual acuity and fluid reduction in patients with diabetic macular edema. Kodiak has advanced KSI-501 into a Phase 3 study DAYBREAK to evaluate its efficacy and safety in wet AMD. DAYBREAK is actively enrolling patients. DAYBREAK uses KSI-501's enhanced 50 mg/mL formulation containing both conjugated and unconjugated antibody that is intended to balance immediacy and durability.

About DAYBREAK and KSI-501:

The DAYBREAK study is a non-inferiority study evaluating parallel investigational arms of KSI-501 and tarcocimab against active comparator aflibercept. Patients randomized to KSI-501 will receive fixed every 8-week dosing with additional individualized dosing (up to monthly dosing) on an as needed basis after 4 monthly loading doses. Patients randomized to aflibercept will be dosed per label. Using the same treat-to-dryness approach as tarcocimab, coupled with fixed intensive proactive dosing, our goal is to maximize both the probability of meeting the primary endpoint as well as the probability of demonstrating additional efficacy benefits. The primary endpoint is non-inferiority in change in visual acuity from baseline to the average of Week 40, 44 and 48. The objective for KSI-501 in DAYBREAK is to explore the efficacy potential of bispecific VEGF and IL-6 inhibition in a broad treatment-naïve wet AMD population. DAYBREAK is now actively enrolling patients. Additional information about DAYBREAK can be found on www.clinicaltrials.gov under Trial Identifier NCT06556368 (<https://clinicaltrials.gov/study/NCT06556368>).

About KSI-101

KSI-101 is a novel, potent and high strength (100 mg/mL) bispecific protein targeting IL-6 and VEGF, which is a "traditional" (unconjugated) intravitreal biologic. We are developing KSI-101 for patients who have retinal fluid and inflammation. Currently there are no available intravitreal biologic therapies addressing the spectrum of inflammatory conditions of the retina. We believe that retinal inflammatory conditions represent a new market segment separate from the established anti-VEGF market. KSI-101 is a clinical prospect with opportunities and risks uncoupled from the ABC Platform, and as such we believe it is an important part of our portfolio.

We continue to enroll patients in our dose-finding Phase 1b study APEX. The APEX study evaluates KSI-101 in two cohorts, Cohort 1 in patients with diabetic macular edema ("DME") and Cohort 2 in patients with macular edema secondary to inflammation ("MESI"). The goal of the APEX study is to evaluate the safety and tolerability of KSI-101 and to identify two dose levels to progress into dual Phase 3 studies (PEAK and PINNACLE) in MESI.

About Kodiak Sciences Inc.

Kodiak Sciences (Nasdaq: KOD) is a biopharmaceutical company committed to researching, developing, and commercializing transformative therapeutics to treat a broad spectrum of retinal diseases. We are focused on bringing new science to the design and manufacture of next generation retinal medicines to prevent and treat the leading causes of blindness globally. Our ABC Platform[®] uses molecular engineering to merge the fields of protein-based and chemistry-based therapies and has been at the core of Kodiak's discovery engine. We are developing a portfolio of three clinical programs, two of which are late-stage today and derived from our ABC Platform and one which is platform-independent and which we believe can progress rapidly into pivotal studies.

For more information, please visit www.kodiak.com.

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Forward-Looking Statements

This release contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. These forward-looking statements are not based on historical fact and include statements regarding: the potential of Kodiak 2.0; timing of topline data; the potential benefits of tarcocimab, KSI-501 and KSI-101; maximizing the probability of success of DAYBREAK; the commercial opportunity and high unmet need for KSI-101; the ABC[®] platform science continuing to advance a next set of investigational therapies for high prevalence retinal diseases; anticipated highlights to be shared in an Investor R&D update in July 2025; the ultimate objective of tarcocimab to provide a flexible 1-month through 6-month label for all patients with retinal vascular disease; tarcocimab's potential to achieve strong efficacy both in treating existing disease and preventing vision threatening complications and disease progression; and guidance on cash runway. Forward-looking statements generally include statements that are predictive in nature and depend upon or refer to future events or conditions, and include words such as "may," "will," "should," "would," "could," "expect," "plan," "believe," "intend," "pursue," and other similar expressions among others. Any forward-looking statements are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. The risks and uncertainties include, but are not limited to: the risk that cessation or delay of any of the on-going clinical studies and our development of tarcocimab, KSI-501 or KSI-101 may occur; the risk that results of our clinical studies may not provide the evidence, insights, or benefits as anticipated; the risk that safety, efficacy, and durability data observed in our product candidates in current or prior studies may not continue or persist; the risk that the results of the tarcocimab Phase 3 studies may not be sufficient to support a single BLA submission for wet AMD, retinal vein occlusion and diabetic retinopathy; the risk that a BLA may not be accepted by, or receive approval from, the FDA or foreign regulatory agencies when expected, or at all; future potential regulatory milestones of tarcocimab or KSI-501 or KSI-101, including those related to current and planned clinical studies, may be insufficient to support regulatory submissions or approval; the risk that our research and development efforts and our ability to advance our product candidates into later stages of development may fail; any one or more of our product candidates may not be successfully developed, approved or commercialized; our manufacturing facilities may not operate as expected; adverse conditions in the general domestic and global economic markets, which may significantly impact our business and operations, including our clinical trial sites, as well as the business or operations of our manufacturers, contract research organizations or other third parties with whom we conduct business; as well as the other risks identified in our filings with the Securities and Exchange Commission. For a discussion of other risks and uncertainties, and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in our most recent Form 10-K, as well as discussions of potential risks, uncertainties, and other important factors in our subsequent filings with the Securities and Exchange Commission. These forward-looking statements speak only as of the date hereof and Kodiak undertakes no obligation to update forward-looking statements, and readers are cautioned not to place undue reliance on such forward-looking statements. Kodiak[®], Kodiak Sciences[®], ABC[®], ABC Platform[®], ABCD[™] and the Kodiak logo are registered trademarks or trademarks of Kodiak Sciences Inc. in various global jurisdictions.

Kodiak Sciences Inc.

Condensed Consolidated Statements of Operations

(Unaudited)

(in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2025	2024
Operating expenses		
Research and development	\$ 43,644	\$ 29,931
General and administrative	15,429	16,124
Total operating expenses	59,073	46,055
Loss from operations	(59,073)	(46,055)
Interest income	1,602	3,353
Other income (expense), net	10	(337)

Net loss and comprehensive loss	\$ (57,461)	\$ (43,039)
Net loss per common share, basic and diluted	\$ (1.09)	\$ (0.82)
Weighted-average shares of common stock outstanding used in computing net loss per common share, basic and diluted	52,746,318	52,510,460

Kodiak Sciences Inc.
Condensed Consolidated Balance Sheet Data
(Unaudited)
(in thousands)

	March 31, 2025	December 31, 2024
Cash and cash equivalents	\$ 138,851	\$ 168,074
Working capital	111,809	146,363
Total assets	297,909	335,578
Accumulated deficit	(1,386,199)	(1,328,738)
Total stockholders' equity	108,842	150,288

 View original content: <https://www.prnewswire.com/news-releases/kodiak-sciences-announces-recent-business-highlights-and-first-quarter-2025-financial-results-302455804.html>

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